Quality of life and health status in patients with intermittent claudication

Breek, J.C.

Publication date:
2004

Document Version
Publisher's PDF, also known as Version of record

QUALITY OF LIFE and HEALTH STATUS in patients with INTERMITTENT CLAUDICATION

J.C. Breek

QUALITY OF LIFE

and

HEALTH STATUS

in patients with

INTERMITTENT CLAUDICATION

The study and the publication of this thesis were supported by grants from:
Stichting Voorziening voor Wetenschappelijk Onderzoek Tilburg, Cook Nederland B.V., W.L. Gore & Associates B.V., Sanofi-Synthelabo B.V., and Vascutek Nederland B.V.

Printed by: Stichting C. Regenboog, Groningen, The Netherlands

Cover: Protagoras of Abdera

ISBN 90-9017722-1

QUALITY OF LIFE

and

HEALTH STATUS

in patients with

INTERMITTENT CLAUDICATION

Proefschrift

Ter verkrijging van de graad van doctor
aan de Universiteit van Tilburg,
op gezag van de rector magnificus,
prof. dr. F.A. van der Duyn Schouten.
In het openbaar te verdedigen
ten overstaan van een door het
college voor promoties aangewezen commissie
in de aula van de Universiteit op
vrijdag 23 januari 2004 om 14.15 uur

door

Johannes Cornelis Breek

geboren op 30 maart 1960 te Amsterdam

Promotor:
Prof. dr. G.L.M. van Heck

Copromotores:
Dr. J.F. Hamming
Dr. J. de Vries

"Off all things the measure is man, of the things that are, that they are, and of the things that are not, that they are not." (DK80b1)

Protagoras of Abdera (c.490 - c.420 BCE)

Contents

CHAPTER 1

GENERAL INTRODUCTION, AIMS, AND DESIGN OF THE STUDY

INTRODUCTION

The manifestations of peripheral arterial occlusive disease (PAOD) range from mild limitations in walking capacity, as in intermittent claudication (IC), to gangrenous tissue loss of the lower limb with ultimately the risk of amputation. The surgical treatment of PAOD has been characterised by endeavours to overcome the obstacles of arterial blood flow. With the development of vascular surgical techniques and subsequent better long term-results, invasive treatment became popular, though sometimes at the cost of complications[1-3]. Recognising the generally benign course of IC for the legs, the hazards of invasive treatment, and the high mortality of patients with atherosclerosis, a more conservative approach was adopted for patients with mild symptoms, in the last decades of the 20th century[4,5].

Because of the initial emphasis on invasive therapy, the vascular literature has been dominated for a long time by technical issues disregarding disease impact and treatment results as experienced by patients. Although hard endpoints and the means to achieve them are important from a traditional surgical point of view, it can be debated whether they have a relationship with patients' perception of disease and treatment results[6]. This becomes even more important if one considers that IC is a herald of potentially life-threatening atherosclerotic complications[7]. This questions the appropriateness of the arguments on which treatment plans are currently based. For instance, do these arguments represent the actual problems for which the patient seeks help? Does treatment provide a solution for those problems? The staff of the vascular unit of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands realised that treatment decisions in patients with IC were not always based on consistent arguments and wanted to systematically study the patients' perception of disease impact and treatment results. Based on the literature, it was assumed that the impact of IC on daily life should be assessed by means of quality of life (QOL) measures. With the aim to optimise the methodology of the study, efforts were joined with the Department of Psychology and Health of Tilburg University, Tilburg, The Netherlands, which has a specific interest for and wide experience with the development and application of QOL measures.

INTERMITTENT CLAUDICATION

Intermittent claudication (IC) is the clinical condition of lower extremity muscle pain induced by exercise and relieved by short periods of rest[8]. The pain never starts at rest nor disappears while walking. IC is a manifestation of peripheral arterial occlusive disease (PAOD), caused by the atherosclerotic process of progressive narrowing of arteries. Failure of the arterial system to supply an adequate blood flow to meet the metabolic demands of exercising muscles, results in a progressive oxygen debt, experienced by the patient as

cramping muscle pain. The development and course of PAOD and IC are accelerated by the same cardiovascular risk factors that are associated with other expressions of atherosclerotic disease, such as coronary heart disease and cerebrovascular disease. There is convincing evidence for an association between IC and the traditional atherosclerotic risk factors smoking, diabetes mellitus, hypertension, and hyperlipidaemia, as well as more recently identified factors like plasma fibrinogen levels, insulin tolerance and hyperhomocysteinaemia[9,10].

Epidemiology of intermittent claudication

The incidence and prevalence of PAOD and IC are difficult to calculate, because of the different criteria used and the varying size and methodology of studies. Besides, not all patients with PAOD will report symptoms of IC. A low activity level may not provoke symptoms and elderly patients often consider their complaint as part of ageing and consequently do not report symptoms. Since only a small proportion of patients will seek medical advice, of which a minority will be referred for further evaluation, incidence based on hospital referrals probably underestimates the real incidence of IC[11]. The incidence of IC in men increases with age from 2 per 1000 per year in the age 35-39 years to 7 per 1000 per year in the age 70-74 years[12-16] (Fig. 1). In the Netherlands, the incidence in men ranges between 4 (55-59 years) and 13 per 1000 per year (>85 years). In women, the numbers range from 3 to 8 per 1000 per year in the same age categories[17].

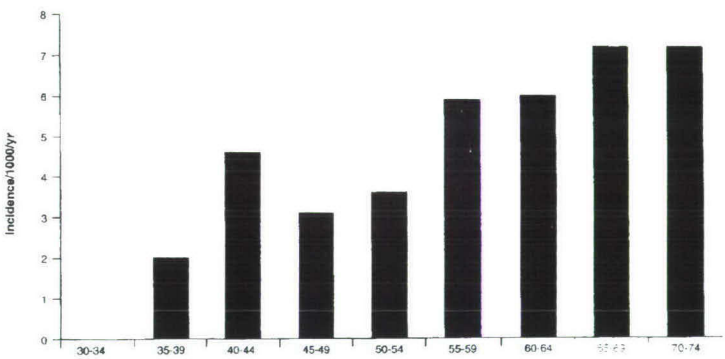


Figure 1
Weighted mean incidence of intermittent claudication in men found in five large population-based studies (Reprinted from TASC working group. Management of peripheral arterial disease. Epidemiology, natural history, risk factors. Eur J Vasc Endovasc Surg 2000;19:S4-S30, with permission from Elsevier)

The prevalence of IC increases with age, and men are more affected than women[18-24]. In large international studies, the prevalence of IC in men around the age of 60 years is estimated between 3% and 6% (Fig. 2). In the Netherlands, symptomatic PAOD has a prevalence of 4.7 per 1000 (5.1 in men, 4.2 in women) for all age categories[25]. The prevalence of both symptomatic and asymptomatic PAOD for all age categories is estimated around 2%, increasing with age to 6.9% (men 7.2%, women 6.5%) in the category 45-75 years, of which about one fifth will have symptoms of IC[26].

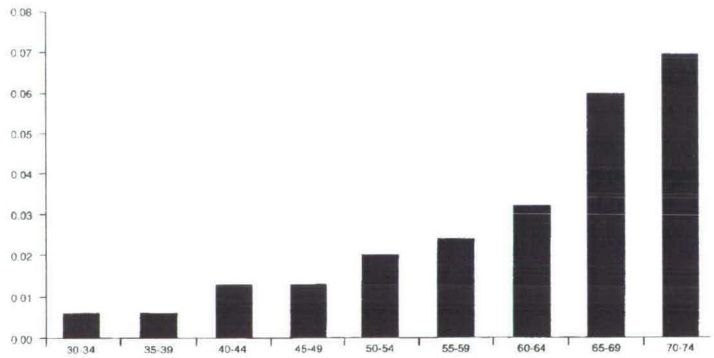


Figure 2
Weighted mean prevalence of intermittent claudication in men in large population-based studies (Reprinted from TASC working group. Management of peripheral arterial disease. Epidemiology, natural history, risk factors. Eur J Vasc Endovasc Surg 2000;19:S4-S30, with permission from Elsevier)

The medical expenditure as a result of IC is illustrated by the fact that, in the year 2000, PAOD accounted for 6% of all hospital admittances for cardiovascular disease in the Netherlands, of which 1.3% for IC (> 3400 patients hospitalised and > 2100 patients admitted in one day-care)[27]. The number, character, and costs of diagnostic procedures vary widely between hospitals and countries and are difficult to compare. Treatment strategies for IC range between cheap non-supervised exercise training and expensive surgical or endovascular procedures. Similarly, the low costs for antiplatelet therapy to prevent further atherosclerotic events will increase significantly with the prescription of additional antihypertensive drugs, statins, and more or less effective agents to improve the walking distance. As a consequence, the costs of diagnosis and treatment of IC, and those of follow-up and secondary prevention are difficult to calculate, but probably substantial[28].

Natural history of intermittent claudication

Although PAOD is progressive, IC generally has a benign course for the legs. In more than half of the patients, symptoms will improve or disappear after five years. One fourth of the patients will deteriorate, most often in the first year after diagnosis (6%-9%), falling to 2%-3% per year thereafter[29-31]. Major amputation is a rare outcome for claudication, with a risk of 1 to 3% over a 5-year period[32-34].

Since atherosclerosis is a systemic disease affecting all arteries, symptoms are not confined to the lower limbs. There is an important overlap between PAOD, coronary heart disease, and cerebrovascular disease[35,36] (Fig. 3).

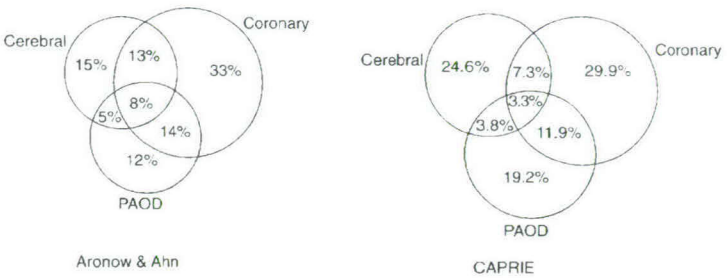


Figure 3

Overlap between peripheral arterial occlusive disease, coronary artery disease (CAD), and cerebrovascular (CVD) disease in 1886 patients aged > 62 years, 37% of whom had no clinical evidence of CHD, CVD or PAOD. Adapted from Aronow and Ahn[35] and CAPRIE[36] (Reprinted from Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999;12:123-137, with permission from Elsevier)

Overall, up to 60% of the patients with IC will have coronary or cerebrovascular disease and in one fifth fatal cardiac or cerebrovascular complications will occur within five years after the onset of symptoms. Conversely, about 40% of the patients with coronary or cerebrovascular disease also will have PAOD[29,30,37]. As a result, the mortality of patients with IC is two to three times higher than in the age-matched healthy population, i.e., 30% at five years, 50% at ten years, and 70% at 15 years. This decreases the mean life expectancy of patients with IC by 10 years[38] (Figs. 4 and 5).

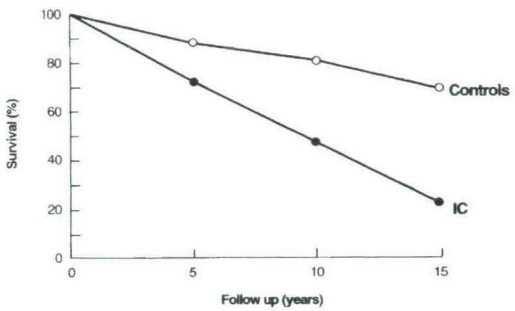


Figure 4
Mean survival curves of patients with intermittent claudication and matched controls within 15 years follow-up (Reprinted from Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999;12:123-137, with permission from Elsevier)

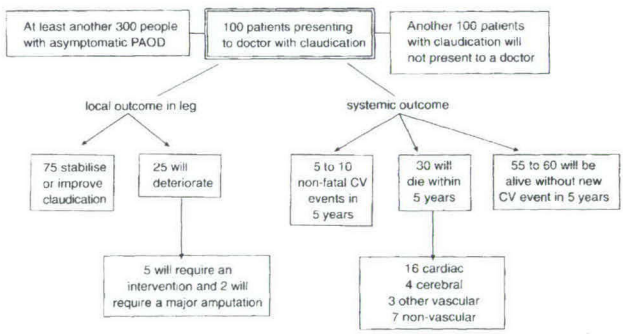


Figure 5
Summary of fate of the claudicant over 5 years from presentation (Reprinted from Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999;12:123-137, with permission from Elsevier)

Diagnostic procedures for intermittent claudication

The diagnosis IC is based on history and physical examination and may be confirmed by functional tests. A history of cramping muscle pain, usually in the calves, after walking a certain distance, that disappears gradually after cessation of the exercise is suggestive for IC. Questionnaires for the identification of IC have been developed, like the World Health Organisation/ Rose Questionnaire and the Edinburgh Claudication Questionnaire[39,40] (Table 1).

Table 1
Edinburgh modification of the Rose questionnaire

1. Do you get a pain or discomfort in your leg(s) when you walk?
   (No: stop)
2. Does the pain ever begin when you are standing still or sitting?
3. Do you get it if you walk uphill or hurry?
4. Do you get it when you walk at an ordinary pace on the level? (Used for grading the severity of I.C.)
5. What happens to it if you stand still?
   Usually continues more than 10 minutes
   Usually disappears in 10 minutes or less
6. Where do you get this pain or discomfort?

On physical examination, the absence of peripheral pulses and bruits over the femoral artery are suggestive for the diagnosis. However, there may be palpable peripheral pulses in symptomatic patients with moderate disease. A useful non-invasive test for diagnosing IC is the Doppler ankle/ brachial blood pressure index (ABPI). At a cut off value of 0.9, the ABPI appeared up to 95% sensitive in detecting angiogram-positive disease and almost 100% specific in identifying apparently healthy individuals[41-46]. The key modality to the diagnosis of symptomatic IC is the treadmill test[47-48]. For the diagnosis IC, the exercise must provoke the typical pain and show a concomitant ABPI drop of at least 20 mm Hg on the symptomatic side[49]. Although there are doubts about the reliability of measuring claudication distances with a treadmill, because of daily fluctuations in severity of IC and the influence of vascular technicians, the test offers the possibility to differentiate between patients with a walking limitation as a result of IC and those who are limited by other complaints like back, hip, and knee symptoms, and cardiopulmonary disease[50].
The degree of IC, the severity of the walking impairment, is traditionally expressed in the stages IIA and IIB of the Leriche-Fontaine classification (Table 2).

Table 2
Leriche-Fontaine classification of peripheral arterial occlusive disease

Stage I	Disease on angiography, no symptoms
Stage II	Intermittent claudication
IIA	Pain free walking distance $\geq$ 100 m.
IIB	Pain free walking distance $<$ 100 m.
Stage III	Rest pain or pain at night
Stage IV	Tissue loss

More recently, the International Society for Vascular Surgery/ The North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS) has proposed an alternative classification, based on treadmill performance and ankle blood pressures before and after exercise[49] (Table 3).

Table 3
Suggested classification for grading the severity of chronic arterial occlusive disease (SVS/ISCVS[49])

Grade	Category	*Clinical description*	*Objective criteria*
0	0	Asymptomatic-no haemodynamically significant occlusive disease	Normal treadmill or reactive hyperaemia test
0	1	Mild claudication	Completes treadmill exercise* AP after exercise >50 mm Hg but at least 20 mm Hg lower than resting value
1	2	Moderate claudication	Between categories 1 and 3
1	3	Severe claudication	Cannot complete standard treadmill exercise* *and* AP after exercise <50 mm Hg
2	4	Ischaemic rest pain	Resting AP <40 mm Hg, flat/ barely pulsatile ankle or metatarsal PVR;TP <30mmHg
3	5	Minor tissue loss-non-healing ulcer, focal gangrene with diffuse pedal ischaemia	Resting AP <60 mm Hg, ankle or metatarsal PVR flat/ barely pulsatile; TP <40 mm Hg
3	6	Major tissue loss-extending above TM level, functional foot no longer salvageable	Same as category 5

*Five minutes at 2 mph on a 12% incline. Note: AP = ankle pressure, TP = toe pressure, PVR = pulse volume recording, TM = transmetatarsal

Complementary to the objective assessment of IC, the Walking Impairment Questionnaire (WIQ) has been developed, permitting patients to quantify their walking ability in terms of defined distances and speeds and to rate the severity of claudication pain during usual walking activities[51].

Treatment of intermittent claudication

Most important for the management of patients with IC is to recognise that they are at risk of developing severe and often fatal cardiovascular complications. The first priority should be to modify the known risk factors for the progression of atherosclerosis and development of subsequent complications. It is important to explain to the patient the rationale for this strategy and that it is not designed to improve the claudication distance[52].

The cornerstone of treatment for patients with IC is cessation of smoking, exercise training, and anti-platelet medication for the secondary prevention of atherosclerotic events[53-57]. It has been reported that smoking cessation is associated with a declining incidence of IC and that the risk of IC for ex-smokers might decrease after one year[58,59]. Exercise training is most effective in a supervised setting, 3 to 5 times a week 35 to 50 minutes, for at least six months. In addition to a 100 to 150% improvement of the maximum walking distance, the regimen confers also some health status benefits[53,56,57,60,61]. Sanitation of cardiovascular risk factors and treatment of comorbidity, like adequate regulation of hypertension, diabetes mellitus,

hyperlipidaemia, and overweight, will contribute to a better physical condition too[62,63]. Despite reports on statistically significant, but clinically moderate benefits for walking (less than 100 m.) and even health status[64-66], pharmacological treatment of IC is not widely accepted[67-68].

The decision to consider interventional therapy should be based on the actual handicap, which may vary substantially between patients, and is difficult to assess. Assessment at the most individual level, e.g. by means of quality of life (QOL) measurements, may contribute to patient-tailored treatment. If conservative treatment fails, short isolated lesions in the iliac arteries, and to a lesser extent in the femoropopliteal segment, may be treated with percutaneous transluminal angioplasty (PTA). The procedure has low morbidity and mortality risks (<0.5%) and, at 5 years, patency rates have been reported of 80 to 90% for iliac lesions and 60 to 70% femoropopliteal lesions[69-71]. However, a meta-analysis on PTA with or without additional stent placement in the iliac arteries reported patency rates that were much lower[72]. The long-term results of femoropopliteal PTA in claudicants appeared also disappointing[73]. Walking improvements are comparable with those of exercise training and health status improvements approach those of surgery[57,61,74,75]. Longer or multi-level lesions require operative interventions[57,76], which, at the cost of a certain morbidity (5-10%) and mortality (2-3%), may provide a 75 to 100% improvement of the maximum walking distance[57]. It has been shown that additional exercise training after bypass surgery enhances the walking benefits[77].

QUALITY OF LIFE RESEARCH

Increasingly, clinicians recognise that illness does not exist in a vacuum, but should be regarded in the context of daily life[78]. This is especially the case in chronic non-lethal diseases with an important impact on daily life, like inflammatory bowel disease[79], chronic lung disease[80], rheumatoid arthritis[81], and peripheral vascular disease[82]. In order to assess this personal context QOL measures could be used[83]. The term has a certain attraction since it has become accepted that health means more than the absence of disease and infirmity, but also reflects a state of physical, psychological, and social well-being[84]. Moreover, it has been recognised that the impact of disease on patients' daily life cannot always be assessed adequately with the traditional instruments[85,86].

To understand reports on QOL, it is necessary to know what is meant by QOL, because the term is frequently used in a confusing way in the medical literature for concepts like health status, health-related QOL, and QOL. In contrast with broad QOL instruments, health-related QOL instruments focus only on health-related issues. Health status assesses the objective influence of disease on physical, psychological, and social functioning[87], whereas QOL is defined by the WHO as "an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations,

standards and concerns. It is a broad ranging concept incorporating in a complex way the individual's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment"[88]. QOL measures are increasingly regarded as a supplement to objective clinical measures of disease, for the assessment of the quality of service, the need for health care, the effectiveness of interventions, and evaluations of economic aspects[89,90]. The potential benefit for the patients is that their problems are identified and dealt with, and that treatment decisions are based on individual priorities and preferences. In other words, the reason for using QOL measures in clinical practice is to ensure that treatment plans and evaluations focus on the patient rather than on the disease. This patient-centred perspective of disease impact and treatment results may contribute to tailor common therapies to the needs of individuals or specific patient groups.
In vascular disease, the traditional outcome measures are walking distance, ankle-brachial blood pressure indices, patency of revascularisation procedures, amputation, and survival[49]. Recognising that atherosclerosis is a chronic progressive and still incurable disease, the treatment of patients with IC is palliative, at best. Practically, this means that the alleviation of symptoms and limitation or modification of disease impact on the patient's daily life remain as goals of treatment[82,91]. A wealth of literature reporting on "QOL" in patients with IC is presently available. Unfortunately, the term QOL is seldom specified in reports that claim to measure QOL. Because high or low scores on measures of functional status or health status are often erroneously equated with good or bad QOL[92], the impact of IC and the influence of various treatment modalities on QOL in patients with IC are still unclear.

AIMS AND DESIGN OF THE STUDY

Considering the inappropriateness of traditional outcome measures for the claudicant's perception of disease and treatment results and the confusion about the use and interpretation of the term "QOL" in the literature, it was decided to perform a study that aims (i) to assess the impact of IC on patients' daily life by means of defined QOL measures, (ii) to identify factors that are of particular importance for QOL in patients with IC, (iii) to explore the similarities and differences between health status and QOL as defined by the WHO, and (iv) to report on the results of conservative treatment in patients with IC, with regard to walking performance, QOL, and health status.
Between January 1999 and June 2001, QOL and health status were assessed prospectively and longitudinally in all patients with IC that were referred to the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands and who agreed to participate in the study by informed consent. The diagnosis IC was suspected on history and physical examination in 215 patients and could be confirmed by treadmill performance and ankle brachial pressure indices in 207 patients. Seven patients refused or were not capable (demented, blind, deaf) to participate. Thus, two hundred patients

completed the World Health Organisation Quality of Life Assessment Instrument-100 (WHOQOL-100) (Appendix I)[93,94]. The WHOQOL-100 was chosen, because it corresponds best with the subjective character of the WHO definition of QOL[88]. It is a generic, multidimensional, self-report measure assessing 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, and Spirituality/religion/personal beliefs), and a generic evaluative facet "Overall QOL and general health". The instrument has been developed simultaneously and cross-culturally in 15 centres around the world and has good psychometric properties[88,95]. Because the chosen QOL measure, WHOQOL-100, was expected to be too long for the elderly IC population, the first step was to select the aspects of daily life that are relevant for patients with PAOD.
Health status was assessed with the RAND-36 item health survey[96,97] (Appendix II) which is practically identical to the Medical Outcome Study/Short Form-36 (SF-36)[98]. The instrument was chosen because of its proven applicability in PAOD and to comply with the recommended standardisation of reporting health status in vascular disease[82,99,100]. The RAND-36 is a 36-questions generic health status measure, assessing health in eight dimensions: Physical functioning, Social functioning, Limitations in usual role activities due to physical problems (Role physical), Limitations in usual role activities due to emotional problems (Role emotional), Mental health, Vitality, Bodily pain, and General health perception.
To place the results in perspective, patients were matched for age and sex with healthy controls. The scores of the matched controls were collected from the WHOQOL data base of the Department of Psychology and Health of Tilburg University, Tilburg, The Netherlands and from the RAND-36 database of the Northern Centre for Health Care Research, Groningen, The Netherlands. In all patients, risk factors and comorbidity were recorded according to the recommended standards for reports dealing with lower extremity ischaemia[49].

OUTLINE OF THE THESIS

The aforementioned study aims and results will be presented in the thesis in the following chapters. Chapter 2 contains a review of the present literature on health status and QOL in patients with IC. In the review, an attempt is made to (i) clarify the differences between several concepts that are labelled QOL, (ii) describe the measures that are used to assess these concepts in patients with IC, (iii) provide an overview of the published study results in patients with IC, and (iv) prelude on the implementation of subjective outcome measures in the treatment of patients with IC.
Chapter 3 concerns a pilot study that was performed to analyse the process of measuring QOL and health status, using the WHOQOL-100 and the RAND-36 questionnaires in patients with varying degrees of lower limb ischaemia. The main question concerned the appropriateness of the WHOQOL-100 for the assessment of QOL in patients with PAOD. The second goal of the study was to shorten the questionnaire to reduce patient burden by

removing aspects that were not relevant to patients with PAOD. Finally, special attention was given to practical problems that were encountered during completion of the questionnaires.
Chapter 4 addresses similarities and differences between QOL and health status, and the possible advantages of combined use for the assessment of disease impact in patients with IC. At the first visit to the vascular outpatient clinic, 200 patients completed the reduced version of the WHOQOL-100 and the RAND-36. Patients' results on these measures were compared with each other and with the results of age and sex-matched healthy persons.
Chapter 5 contains the first report on QOL, as measured with the reduced version of the WHOQOL-100, in 151 patients with IC. In addition, the effects of the severity of IC on QOL were examined.
Chapter 6 deals with the key question for QOL in claudicants, i.e., which are the factors that are responsible for the QOL of patients with IC? Is QOL determined by the walking problem or are there other factors that influence QOL in patients with IC? Using multiple regression analyses, the predictive value of age, sex, degree of IC, cardiovascular risk factors and comorbidity, as well as the presence of back, hip, and knee symptoms for QOL in patients with IC were examined.
Chapter 7 reports on the effects of one year of conservative treatment with regard to walking performance, QOL, and health status in patients with IC. In addition, QOL and health status scores before and after treatment were compared with those of age and sex matched healthy persons.
A general discussion on the study results, questions, and considerations that have raised from this study is presented in Chapter 8. The last two chapters contain summaries of this thesis in English, and in Dutch for the non-medical reader.

REFERENCES

1. Szilagyi DE, Elliott JP Jr, Smith RF, Reddy DJ, McPharlin M. A thirty-year survey of the reconstructive surgical treatment of aortoiliac occlusive disease. J Vasc Surg 1986 Mar;3(3):421-36

2. Schepers A, Klinkert P, Vrancken Peeters MP, Breslau PJ. Complication registration in patients after peripheral arterial bypass surgery. Ann Vasc Surg 2003;17(2):198-202

3. Jamsen TS, Manninen HI, Tulla HE, Jaakkola PA, Matsi PJ. Infrainguinal revascularization because of claudication: Total long-term outcome of endovascular and surgical treatment. J Vasc Surg 2003 Apr;37(4):808-15

4. Coffman JD. Intermittent claudication – Be conservative. N Engl J Med 1991;325:577-578

5. Phillipps MJ, Cowan AR, Johnson CD. Intermittent claudication should not be treated by surgery. Ann R Coll Surg Engl 1997;79:264-267

6. Chetter IC, Dolan P, Spark JI, Scott DJA, Kester RC. Correlating clinical indicators of lower limb ischaemia with quality of life. Cardiovasc Surg 1997;5:361-366

7. Dormandy J, Heeck L, Vig S. Intermittent claudication: A condition with underrated risks. Sem Vasc Surg 1999;12:96-108

8. Taylor LM, Porter JM. Natural history and nonoperative treatment of chronic lower extremity ischemia. In: Rutherford RB, ed. Vascular Surgery 4th ed, Saunders Company, Philadelphia, 1997

9. Dormandy J, Heeck L, Vig S. Predictors of early disease in the lower limbs. Sem Vasc Surg 1999;12:109-117

10. TASC working group. Management of peripheral arterial disease. Epidemiology, natural history, risk factors. Eur J Vasc Endovasc Surg 2000;19:S4-S30

11. Dormandy J, Mahir M, Ascady G. et al. Fate of the patient with chronic leg ischemia. J Cardiovasc Surg 1989;30:50-57

12. Widmer LK, Da Silva A. Historical perspectives and the Basle study. In: Fowkes FGR, ed. Epidemiology of peripheral vascular disease. London: Springer Verlag, 1991:69-83

13. Leng GC. Questionnaires. In: Fowkes FGR, ed. Epidemiology of peripheral vascular disease. London: Springer Verlag, 1991:29-40

14. Bainton D, Sweetman P, Baker I, Elwood P. Peripheral arterial disease: consequences for survival and association with risk factors in the Speedwell prospective heart disease study. Br Heart J 1994;72:128-132

15. Bowlin SJ, Medalie JH, Flocke SA, Zyzanski SJ, Goldbourt U. Epidemiology of intermittent claudication in middle-aged men. Am J Epidemiol 1994;140:418-430

16. Murabito JM, D'Agostino RB, Silbershatz H, Wilson WF. Intermittent claudication: A risk profile from the Framingham heart study. Circulation 1997;96:44-49

17. Meyer WT, Cost B, Bernsen RM, Hoes AW. Incidence and management of intermittent claudication in primary care in the Netherlands. Scan J Prim Health Care 2002;20:33-34

18. Hughson WG, Mann JI, Garrod A. Intermittent claudication: Prevalence and risk factors. Br Med J 1978;1:1379-1381

19. De Backer IG, Kornitzer M, Sobolski J, Denolin H. Intermittent claudication: Epidemiology and natural history. Acta Cardiol 1979;34:115-124

20. Reunanen A, Takkunen H, Aromaa A. Prevalence of intermittent claudication and its effects on mortality. Acta Ned Scand 1982;211:249-256

21. Fowkes FGR, Housley E, Cadwood EH, Macintyre CC, Ruckley CV, Prescott RJ. Edinburgh artery study: Prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. Int J Epidemiol 1991;20:384-392

22. Stoffers HEJH, Kaiser V, Knottnerus JA. Prevalence in general practice. In: Fowkes FGR, ed. Epidemiology of peripheral vascular disease. London: Springer Verlag, 1991:109-115

23. Smith WCS, Woodward M, Tunstall-Pedoe H. Intermittent claudication in Scotland. In: Fowkes FGR, ed. Epidemiology of peripheral vascular disease. London: Springer Verlag, 1991:117-123

24. Novo S, Avellone G, Di Garbo G. et al. Prevalence of risk factors in patients with peripheral arterial disease: A clinical and epidemiological evaluation. International Angiology 1992;11:218-229

25. Oskam SA, Brouwer HJ, Mohr J. TRANS, an interactional access program for standard output of the transition project. Amsterdam. Department of General Practice, 1994

26. Rauwerda JA. Ed. Chronische arteriële obstructieve vaatziekten. In: Vaatpatiënten in beeld. Nederlandse Hartstichting, 1998

27. Koek HL, Van Leest LATM, Verschuren WMM, Bots ML. Hart- en vaatziekten in Nederland 2003, cijfers over leefstijl en risicofactoren, ziekte en sterfte. Den Haag: Nederlandse Hartstichting, 2003

28. TASC working group. Management of peripheral arterial disease. Economic aspects of intermittent claudication. Eur J Vasc Endovasc Surg 2000;19 :S104-S108

29. O'Riordain DS, O'Donnel JA. Realistic expectations for the patient with intermittent claudication. Br J Surg 1991;78:861-863

30. Hertzer NR. The natural history of vascular disease. Circulation 1991;83(suppl I):I-12-I-19

31. Leng GC, Lee AJ, Fowkes FG. et al. Incidence, natural history and cardiovascular events in symptomatic and asymptomatic peripheral arterial disease in the general population. Int J Epidemiol 1996;25:1172-1181

32. Breslau PJ, Jorning PG, Dassen P. The natural history of intermittent claudication, a prospective study. Presented at the 2nd International Vascular Symposium. September 1986

33. Gilliland LE, Llewellyn CD, Goss DE. et al. The morbidity and mortality of stable claudicants: Results of five year follow-up. Presented at the 2nd International Vascular Symposium. September 1986

34. McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. Ann Vasc Surg 1989;3:273-277

35. Aronow WS, Ahn C. Prevalence of coexistence of coronary artery disease, peripheral arterial disease, and atherothrombotic brain infarction in men and women ≥62 years of age. Am J Cardiol 1994;74:64-65

36. CAPRIE Steering committee: A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischemic events (CAPRIE). Lancet 1996;348:1329-1339

37. Dormandy JA, Murray GD. The fate of the claudicant – A prospective study of 1969 claudicants. Eur J Vasc Surg 1991;5:131-133

38. Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999;12:123-137

39. Rose GA. The diagnosis of ischaemic heart pain and intermittent claudication in field surveys. Bull WHO 1962;27:645-658

40. Leng GC, Fowkes FGR. The Edinburgh Claudication Questionnaire: An improved version of the WHO/Rose Questionnaire for use in epidemiological surveys. J Clin Epidemiol 1992;45:1101-1109

41. Winsor T. Influence of arterial disease on the systolic blood pressure gradients of the extremity. Am J Med Sci 1950;220:117-126

42. Carter SA. Indirect systolic pressures and pulse waves in arterial occlusive disease of the lower extremities. Circulation 1968;37:624-638

43. Yao ST. New techniques of objective arterial evaluation. Arch Surg 1973;106:600-604

44. Hummel BW, Hummel BA, Mowbry A. et al. Reactive hyperaemia vs. treadmill exercise testing in arterial disease. Arch Surg 1978;113:95-98

45. Ouriel K, McDonnel AE, Metz CE. et al. A critical evaluation of stress testing in the diagnosis of peripheral vascular disease. Surgery 1982;91:686-693

46. Laing S, Greenhalgh RM. The detection and progression of asymptomatic peripheral arterial disease. Br J Surg 1983;70:628-630

47. Hiatt, WR, Hirsch AT, Regensteiner JG, Brass EP. Clinical trials for claudication. Assessment of exercise performance, functional status and clinical endpoints. Circulation 1995;92:614-621

48. Cachovan M, Rogatti W, Creutzig A. et al. Treadmill testing for evaluation of claudication: Comparison of constant-load and graded-exercise tests. Eur J Vasc Endovasc Surg 1997;14:238-243

49. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538

50. Watson CJE, Phillips D, Hands L, Collin J. Claudication distance is poorly estimated and inappropriately measured. Br J Surg 1997;84:1107-1109

51. Regensteiner JG, Steiner JF, Panzer RJ, Hiatt WR. Evaluation of walking impairment by questionnaire in patients with peripheral arterial disease. J Vasc Biol 1990;2:142-152

52. TASC working group. Management of peripheral arterial disease. Treatment of intermittent claudication. Eur J Vasc Endovasc Surg 2000;19 :S67-S76

53. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain. A meta-analysis. JAMA 1995 Sep 27;274(12):975-80

54. Remijnse-Tamerius HC, Duprez D, De Buyzere M, Oeseburg B, Clement DL. Why is training effective in the treatment of patients with intermittent claudication? Int Angiol 1999 Jun;18(2):103-12

55. Tan KH, De Cossart L, Edwards PR. Exercise training and peripheral vascular disease. Br J Surg 2000 May;87(5):553-62

56. Leng GC, Fowler B, Ernst E. Exercise for intermittent claudication. Cochrane database Syst Rev 2000;2:CD000990

57. Stewart KJ, Hiatt WR, Regensteiner JG, Hirsch AT. Exercise training for claudication. N Engl J Med 2002;347:1941-1950

58. Ingolfsson IO, Sigurdson G, Sigvaldason H, Thorgeirsson G, Sigdusson N. A marked decline in the prevalence and incidence of intermittent claudication in Icelandic men 1968-1986: A strong relationship to smoking and serum cholesterol- The Reykjavik Study. J Clin Epidemiol 1994;47:1237-1243

59. Dagenais GR, Maurice S, Robitaille NM, Gingras S, Lupien PJ. Intermittent claudication in Quebec men from 1974-1986: The Quebec Cardiovascular Study. Clin Invest Med 1991;14:93-100

60. Regensteiner JG, Hargarten ME, Rutherford RB, Hiatt WR. Functional benefits of peripheral vascular bypass surgery for patients with intermittent claudication. Angiology 1993;4:1-10

61. Feinglass J, McCarthy WJ, Slavensky R, Manheim LM, Martin GJ. Functional status and walking ability after lower extremity bypass grafting or angioplasty for intermittent claudication: Results from a prospective outcomes study. J Vasc Surg 2000;31:93-103

62. Creager MA. Medical management of peripheral arterial disease. Cardiol Rev 2001 Jul-Aug;9(4):238-45

63. Regensteiner JG, Hiatt WR. Current medical therapy for patients with peripheral arterial disease: A critical review. Am J Med 2002;112:49-57

64. Beebe HG, Dawson DL, Cutler BS. et al. A new pharmacological treatment for intermittent claudication: Results of a randomized, multicenter trial. Arch Intern Med 1999 Sep 27;159(17):2041-50

65. Dawson DL, Cutler BS, Hiatt WR. et al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. Am J Med 2000;109(7):523-30

66. Brevetti G, Annecchini R, Bucur R. Intermittent claudication. Pharmacoeconomic quality of life aspects of treatment. Pharmacoeconomics 2002;20(3):169-181

67. Tjon JA, Riemann LE. Treatment of intermittent claudication with pentoxifylline and cilostazol. Am J Health Syst Pharm 2001 Mar 15;58(6):485-93

68. Hiatt WR. Medical treatment of peripheral arterial disease and claudication. New Engl J Med 2001;344:1608-1621

69. Gallino A, Mahler F, Probst P, Nachbur B. Percutaneous transluminal angioplasty of the arteries of the lower limbs; A five year follow-up. Circulation 1984;70:619-623

70. Van Andel GJ, Van Erp WFM, Krepel VM, Breslau PJ. Percutaneous transluminal dilatation of the iliac artey. Long-term results. Radiology 1985;156:321-323

71. Krepel VM, Van Andel GJ, Van Erp WFM, Breslau PJ. Percutaneous transluminal angioplasty of the femoropopliteal artery. Initial and long-term results. Radiology 1985;156:325-328

72. Bosch JL, Hunink MG. Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease. Radiology. 1997 Jul;204(1):87-96

73. Jamsen TS, Manninen HI, Jaakkola PA, Matsi PJ. Long-term outcome of patients with claudication after balloon angioplasty of the femoropopliteal arteries. Radiology. 2002 Nov;225(2):345-52

74. Creasy TS, McMillan PJ, Fletcher EWL, Collin J, Morris PJ. Is percutaneous angioplasty better than exercise for claudication? Preliminary results from a prospective trial. Eur J Vasc Surg 1990;4:135-140

75. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Is intermittent claudication improved by PTA? A randomised controlled trial. J Vasc Surg 1997;26:551-557

76. Comerota AJ. Endovascular and surgical revascularization for patients with intermittent claudication. Am J Cardiol 2000;87(12A):34D-43D

77. Lundgren F, Dahllof A, Lundholm K, Schersten T, Volkmann R. Intermittent claudication- Surgical reconstruction or physical training? Ann Surg 1989;209:346-355

78. Higginson IJ, Carr AJ. Using quality of life measures in the clinical setting. BMJ 2001;322:1297-1300

79. Maunder RG, Cohen Z, McLeod RS, Greenberg GR. Effect of intervention in inflammatory bowel disease on health-related quality of life. Dis Colon Rectum 1995;38:1147-1161

80. Curtis JR, Martin DP, Martin TR. Patient-assessed health outcomes in chronic lung disease. Am J Respir Crit Care Med 1997;156:1032-1039

81. Guillemin F. Functional disability and quality-of-life assessment in clinical practice. Rheumatology 2000;39 (suppl. 1):17-23

82. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: revising the paradigm for the 21st century. J Vasc Surg 2000 Dec;32(6):1239-50

83. Bowling A. Measuring disease: A review of disease-specific quality of life measurement scales. Buckingham: Open University Press;1985

84. World Health Organisation. The constitution of the WHO. WHO chronicle 1947;1:29

85. O'Boyle CA. Assessment of quality of life in surgery. Br J Surg 1992;79:395-398

86. Fraser SCA. Quality of life measurement in surgical practice. Br J Surg 1993;80:163-169

87. Bergner DK. Measurement of health status. Med Care 1985;23:696-704

88. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

89. Hays RD, Shapiro MF. An overview of generic health-related quality of life measures for HIV Research. Qual Life Res 1992;1:91-97

90. Carr AJ, Higginson IJ. Measuring quality of life: Are quality of life measures patient centred? BMJ 2001;322:1356-1360

91. Chetter IC, Scott DJA, Kester RC. An introduction to quality of life analysis: The new outcome measure in vascular surgery. Eur J Vasc Endovasc Surg 1998;15:4-6

92. O'Boyle CA. The schedule for the evaluation of individual quality of life (SEIQOL). Int J Ment Health 1994;23:3-23

93. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-1409

94. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University;1995

95. WHOQOL group. The WHOQOL assessment. (WHOQOL: Development and generic psychometric properties). Soc Sci Med 1998;46:1569-1585

96. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-227

97. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: A manual. Groningen: Northern Centre for Health Care Research; 1993

98. Ware JE, Sherbourne CD. The SF-36 Short Form Health status survey 1, conceptual framework and item selection. Med Care 1992;30:473-483

99. Chetter IC, Spark JI, Dolan P. et al. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardization. Eur J Vasc Endovasc Surg 1997;13:597-60

100. TASC working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

CHAPTER 2

QUALITY OF LIFE IN PATIENTS WITH INTERMITTENT CLAUDICATION

A REVIEW

J.C. Breek
J. de Vries*
G.L. van Heck*
J.F. Hamming**

Dept. of Surgery, Martini Hospital, Groningen, The Netherlands
Dept. of Psychology and Health, Tilburg University, Tilburg, The Netherlands*
Dept. of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands**

Submitted

ABSTRACT

Background: Quality of life (QOL) is increasingly used as an outcome measure in patients with intermittent claudication (IC). Different definitions and measures of QOL often prevent a clear interpretation and comparison of study results.

Material and methods: A Medline search until June 2002, using the key words "IC", "QOL" and "health status", was done to identify publications on the development of QOL assessment in patients with IC, and on QOL assessment before and after treatment. Additional publications were obtained from reference lists.

Results and conclusion: Studies on QOL and IC vary with regard to study design, inclusion criteria, size of patient groups, and duration of follow-up. IC has a broad impact on every day life that goes beyond the physical impairments and functional disabilities that are associated with the walking problem. Increasing IC is mainly responsible for the deterioration of the physical aspects of QOL. Treatment may alleviate symptoms and improve aspects of physical functioning and functional status. However, QOL levels after treatment hardly ever approach those of a non-diseased population. Presently, there are no data on the implementation of QOL as guidelines in clinical practice.

INTRODUCTION

Intermittent claudication (IC) is a common expression of peripheral arterial occlusive disease (PAOD), usually with a benign course for the legs[1]. Although the presenting complaint may seem innocent, concomitant coronary and cerebrovascular disease are serious threats to the claudicant's life[2]. The severity of IC is usually assessed by means of treadmill performance and ankle brachial pressure index (ABPI)[3]. However, these objective parameters have a weak correlation with the impact on daily life[4,5] and their measurement is often not reliable[6]. Increasingly, the patients' perception of physical impairment is regarded as a more appropriate way to assess the consequences of disease and effects of treatment[7-9]. This subjective, patient-oriented outcome is generally referred to as quality of life (QOL). The interpretation of studies on QOL is difficult because the term "QOL" is often used as a container concept, labelling concepts like functional status, health status, and quality of life as QOL[10,11]. To avoid confusing terminology, the term QOL is used throughout the present text, unless authors explicitly used other terms.

Unlike the traditional outcome measures in patients with lower limb ischaemia[3], there are no rules for reports dealing with subjective outcome in these patients, although suggestions have been made[9,12,13]. The choice and development of instruments to assess QOL mainly depend on the investigators' preference, which carries the risk of a gap between academic interest and clinical applicability. However, clinical practice must be supplemented with subjective outcome measurements for the assessment of disease severity, for the evaluation of treatment results, and to identify patients' problems other than physical dysfunction[8,13].

This review aims (i) to clarify the differences between several concepts that are labelled QOL, (ii) to describe the measures that are used to assess these concepts in patients with IC, (iii) to provide an overview of the published study results on QOL in patients with IC, and (iv) to prelude on the implementation of patient-oriented outcome measures in the treatment of patients with IC.

METHOD

A Medline search until June 2002 was performed to identify all publications on the development of QOL assessment in patients with IC, and on QOL assessments before and after treatment, using the key words "IC", "QOL" and "health status". The reference lists of publications were scanned for additional papers on the topic.

DEFINITIONS OF QUALITY OF LIFE

The term QOL is generally used for three concepts: (i) functional status, (ii) health status or health-related QOL, and (iii) QOL as defined by the World Health Organisation (WHO).

Functional status concerns physical functioning and refers to the level of performance[14,15], e.g., the walking ability in claudicants. Functional status can be assessed objectively and subjectively in the sense that patients indicate their ability or impairment to perform certain activities. The assessment of disease impact is limited to the physical part of health[15].

Health status is the impact of disease on patients' physical, social, and emotional functioning[16,17]. Health status measures allow patients to indicate objectively which impairments follow from their disease. For instance, the impaired walking ability in claudicants may interfere with social activities and patients' mood. The scores on health status questionnaires are interpreted by health care professionals as good or bad against reference scores from a healthy population.

Quality of Life, as defined by the WHO, is a broader concept comprising the *personal evaluation* of functioning with regard to physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment[18]. In addition to objective functional assessment, QOL allows for personal appraisal of functioning in the perspective of the individual's own expectations and goals in life as well as his/her cultural frame of reference. This means that two patients with comparable restrictions in physical, psychological, and social functioning, and thus a comparable health status, do not necessarily have the same QOL. For instance, the importance of feeling impaired to participate in social activities also depends on individual preferences, which contributes to a person's QOL.

Other concepts that are referred to as QOL are cost-utility and health-utility measures. Quality-adjusted life year (QALY)[19] is an example of a cost-utility measure. A QALY incorporates the value, duration, and probability of a certain health state. The probability of different therapies to achieve this health state can be calculated, permitting economic evaluations.

Health utility measures such as the Rosser index classify health states according to the degree of mobility/disability and pain[20,21]. Since utilities do not permit to evaluate the physical, psychological, and social components of health, these measures may not be regarded as QOL instruments and consequently will not be discussed.

QUALITY OF LIFE ASSESSMENT INSTRUMENTS

General aspects

The WHO has defined health as not being the mere absence of infirmity, but as a state of physical, psychological, and social well-being[22]. To cover this definition, the questionnaires for the assessment of health status and QOL contain at least physical, psychological, and social domains. These domains may be subdivided into smaller components, containing questions that assess a specific element of a domain. The existing measures can be divided into generic, disease-specific, and symptom-specific instruments[23,24].

Generic instruments have been designed to assess QOL across a variety of diseases and populations, allowing comparisons between different diseases and with healthy persons. However, these instruments may be less sensitive to subtle changes in particular aspects of life for a specific patient group.

Disease-specific instruments have been developed for use in a particular patient population or a group of comparable diseases. These instruments consist of domains that concern relevant aspects for patients with a certain disease. Consequently, it is assumed that they may be more sensitive than generic instruments in detecting differences between certain degrees of the particular disease, or may be more responsive to change over time or following treatment. Impact of the disease on aspects of life that are not directly related to the particular disease may be missed.

Symptom-specific instruments allow for a more detailed analysis of a particular symptom in certain diseases (e.g., the Walking Impairment Questionnaire for the assessment of the walking ability in patients with IC[25]). Since the concepts of QOL have been designed to include at least the three above-mentioned domains, symptom-specific measures cannot be regarded as measures of QOL.

Structure of the instruments

For the completion of questionnaires, respondents are requested to consider a certain time frame, usually two to four weeks. Response scales are either more point scales, offering 5-7 alternative responses[26], or visual analogue scales (VAS), which ask the respondent to put a cross on a 10 cm line, ranging from 0 (worst possible) to 100 (best possible). The answers can be expressed as a profile of scores for separate domains and subscales of the instrument, or as a total index score. A profile provides an insight into the aspects that are impaired and thus can be improved. A total index score merely indicates whether QOL is affected, and may be used for calculating cost-utility. The questionnaires may be self-completed, interviewer-assisted, or interviewer administered.

Validation of instruments

Before application, a measure is subjected to a validation process, testing the instrument for validity, reliability, and responsiveness[27]. Validity reflects how well an instrument actually measures what it intends to measure. Reliability indicates to what extent a measure is free of error. Responsiveness/sensitivity to change represents the ability of an instrument to discriminate between different degrees of severity of a disease or detect meaningful changes over time. Furthermore, an instrument should be practical and comprehensive. The questions should not be confusing in order to assure that the content is well understood and the questionnaire is fully completed. The instrument must comply with an elderly population and also be suitable for patients with a low educational level.

The application of measures into other languages than the original version requires forward-backward translation, consideration of the relevance of aspects that are of particular importance for the new population to be studied, and full revalidation to make the instrument applicable in another country or culture[28].

Finally, study results will only be relevant if they can be interpreted and translated into clinical consequences, e.g., to adjust treatment options to the aspects of QOL that are of particular importance for patients with IC.

INSTRUMENTS USED IN PATIENTS WITH INTERMITTENT CLAUDICATION

Functional status

Functional status in claudicants can be measured objectively with a treadmill and ABPI measurements or subjectively with specific questionnaires. The walking impairment questionnaire (WIQ)[25] has been developed to assess treatment effects on claudication limited walking ability. The instrument is interviewer-administered and consists of two questions to discriminate between claudication and non-claudication related pain. The severity of claudication pain is rated in questions concerning the impairment experienced in terms of defined distances, speeds, and stair climbing. Summary scores are computed and expressed as a percentage of the maximal score. The WIQ has proven to be valid, reliable, and sensitive to change in patients with IC[29,30].

The peripheral arterial disease physical activity recall questionnaire (PAD-PAR)[31,32] provides a global measure of habitual physical activity levels by estimating the total energy expenditure of the patient under various conditions. The instrument is self-completed and asks the respondent to estimate the number of hours spent each week within the categories sleep, work, house, and leisure. In addition, the intensity of the activity is specified with the use of a list of activities that are classified into categories of intensity, except for sleep. The WIQ and the PAD-PAR only assess physical functioning and thus do not supply information on the psychological and social consequences of IC.

Health status

The generic measures of health status, or health-related QOL, that are most often used in patients with IC are the Medical Outcome Study/ Short Form-36 (SF-36)[33,34], the Euroqol[35], the Sickness Impact Profile (SIP)[36,37], the Nottingham Health Profile (NHP)[38], and the McMaster Health Index Questionnaire (MHIQ)[39] (Table 1).

The SF-36 is a 36-item generic measure assessing health status in eight dimensions and health changes over the last year. The SF-36 may be self-administered or interviewer-administered, either by phone or face-to-face. Responses are obtained by more point scales and yes/no answers. In addition to scores for each dimension (a profile), the testing yields a composite health status index score on a scale from 0 (worst) to 100 (best). The SF-36 is short and sensitive to intervening illness. It has a good reliability and validity[40], also in patients with PAOD[41], and has been used frequently in patients with IC[42-53].

The Euroqol measures the salient features of health as perceived by the general population. The instrument is self-completed and measures five dimensions of health on three levels in five questions, producing a profile score. This profile can be translated into a global index of health status/QOL, using a time trade-off (TTO) derived matrix (based on societal preference)[54]. In addition, the Euroqol incorporates a VAS on which respondents can rate their health status/QOL on a scale from 0 (worst) to 100 (best), producing a second global index (patient's preference). The Euroqol is a valid and reliable instrument that has been developed for use in combination with other measures[55,56]. A disadvantage of the Euroqol is its large ceiling effect, limiting the discriminatory power for improvements[56]. The instrument has been used in several studies concerning patients with IC[41,57-61], and appeared to be valid and reliable, although the responsiveness in these patients was poor[41,62].

The SIP is a measure of sickness-related behavioural dysfunction. There are versions for interviewer-administration and self-administration. The SIP consists of 136 yes/no items, describing limitations experienced "today" in 12 subscales of daily activities. Composite scores for the physical and psychosocial dimension, a total score, and subscales scores are calculated and expressed as the percentage of maximum dysfunction. The higher the percentage, the more severe the limitation. Validation studies showed that the SIP is a valid and reliable instrument, and permits to describe similarities of patient groups as well as to differentiate between these groups[36]. The instrument has been criticised for being less sensitive to improvement than deterioration[63]. The SIP has been used in two studies on health status in patients with IC[64,65].

The NHP is a generic, self-administered instrument assessing health status/QOL in six domains. In a first part of the instrument, 38 yes/no questions that reflect problems with health, produce weighted scores in the six domains (a profile), ranging from 0 (best possible score) to 100 (worst possible score). The second part relates to the impact of perceived health on seven areas of everyday activities: Paid employment, Housework, Family relationships, Sex life, Social life, Hobbies, and Holidays. These are presented as the percentage of affirmative responses. Validation studies indicated that the NHP is valid and reliable in a wide variety of diseases[66],

and especially discriminates between severe and non-severe illness[38]. The responsiveness/ sensitivity of the NHP has been questioned with respect to its ability to differentiate mild symptoms from a disease free state[67]. This so-called "floor effect" has been confirmed in patients with varying degrees of IC for the domain Social isolation[68]. Since the NHP mainly focuses on the negative aspects of health, it has been suggested that it should be considered a measure of distress in the respective dimensions rather than a measure of health[66]. The NHP has been used to assess the impact of disease and to evaluate the effects of treatment in patients with IC[41,68-73]. The instrument appeared to be valid, reliable, and responsive to change in patients with IC[41].

The MHIQ is a self-completed valuational instrument assessing impairments in physical, social, and emotional functioning. There are 59 statements that can be answered with yes/no responses or with a more point scale. The instrument produces an index for all possible combinations of the three dimensions on different levels, representing a percentage of a state of ideal well-being (0 is poor function, 1 is good function). Validation studies showed good reliability and validity for the three dimensions, and responsiveness for the physical dimension[39]. The instrument has been used in several diseases, including IC[74-76].

In several countries and languages, IC-specific health status/QOL measures have been developed and validated, like the Artemis, which consists of the SF-36 and six complementary subscales identified to be of particular interest for patients with IC[77], the Peripheral Arterial Occlusive Disease-86 Questionnaire (PAVK-86)[78], the Claudication Scale (CLAU-S)[79-82], the Vascular Quality of Life Questionnaire (VascuQol)[83], and the ST-22[84]. Except for some reports on treatment effects in pharmacological studies[85-89], there is only scant literature on these new instruments and their practical application[90].

Quality of life

The World Health Organisation QOL assessment instrument-100 (WHOQOL-100) is the only measure of QOL, as defined by the WHO, that has been used in patients with IC. It is a generic, multidimensional, self-report measure, that can also be used interviewer-assisted or interviewer-based. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world. It consists of 100 items assessing 24 facets of QOL within six domains and a generic evaluative facet. Each facet is represented by four questions. Responses are expressed in 5-point scales. Scores on each facet and domain can range from 4 to 20. The instrument produces a profile for all domains and facets. The reliability, validity[11], and sensitivity[91] of the instrument are high, also in healthy elderly[10]. The WHOQOL-100 has been used in a variety of patient groups and in a reduced version in claudicants[92-95].

Recognising the incompleteness of the traditional parameters for rating disease severity and treatment outcome, calls for the development and use of IC-specific health status/QOL assessment instruments have been made repetitively[96,97]. The Transatlantic Inter-Society Consensus Document Working Group (TASC)[13] has recommended the WIQ as a useful

instrument for the assessment of functional outcome. Based on a literature review of generic health status/OQL measures, Beattie et al.[98] preferred the SF-36 over the NHP in assessing health status/QOL in patients with vascular disease for being widely accepted, and more sensitive to some levels of disease. In a comparative study in patients with critical as well as non-critical ischaemia of the lower limbs, the SF-36, the NHP, and the Euroqol appeared to be equally reliable[41]. The validity of the SF-36 and the NHP were superior to the Euroqol, and the SF-36 was the most responsive measure. Therefore, the SF-36 has been recommended as the most appropriate health status/QOL measure in these patients and the European standard. This recommendation is supported by the Society for Vascular Surgery[9] and TASC.

DISEASE IMPACT ON QUALITY OF LIFE IN PATIENTS WITH INTERMITTENT CLAUDICATION

Baseline results obtained with the SF-36 show that patients with IC have a reduced QOL compared with healthy persons, in all dimensions[43,45,49,53,99]. The differences are most striking in the physical aspects of the instrument. Bodily pain and a decline in Physical functioning mainly contribute to the reduction in QOL in older patients with IC[48]. The severity of IC, as measured by maximum walking distance (MWD), is a significant predictor of health for all domains, except for Mental health and Role emotional[43]. The ABPI, higher education, and male sex are positive predictors for the Physical function scores, while the presence of heart, lung, and cerebrovascular disease, knee arthritis, and chronic back pain have a negative predictive value[45].

A Euroqol study on the results of percutaneous transluminal angioplasty (PTA) in patients with IC, showed that patients scored significantly worse before treatment than the general population on all but one of the domains[58]. Chetter et al. demonstrated that increasing lower-limb ischaemia resulted in a significant deterioration in global QOL and all Euroqol domains[5]. Although the correlations between QOL and clinical indicators of limb ischaemia were statistically significant, the correlation coefficient was too low to assume that improvements in clinical indicators would translate into similar QOL benefits. Therefore, it was suggested to assess QOL in patients with lower limb ischaemia independent from its clinical indicators.

In one of the earlier studies on QOL and IC, Arfvidsson et al. used the SIP, excluding claudicants with contraindications for reconstructive surgery[64]. A significant correlation was found between incapacitating IC and a broadly impaired QOL. Compared with a historical group of healthy women, patients with a performance above 70 Watts only differed with regard to Work and Ambulation. It was suggested that other dysfunctions, in addition to the walking impairment, might have an impact on QOL. In a recent study by Taft et al., SIP baseline values confirmed that claudicants are limited in daily functioning, most pronounced for Ambulation, the Physical dimension, Overall SIP, and claudication-specific SIP dysfunction[65].

Table 1
Generic assessment instruments of health status and QOL.

Instrument:	Scales/ subscales	Response scale	Scores
SF-36	Physical functioning Role physical Social functioning Role emotional Mental health Vitality Bodily pain General health	36 more point questions	profile/ index
Euroqol	Pain/ discomfort Mobility Usual activities Self care Anxiety/ depression	5 more point questions and VAS	profile/ index
SIP	*Physical dimension* Ambulation Body care and movement Mobility *Psychosocial dimension* Emotional behaviour Social interactions Alertness behaviour Communication Eating Work Sleep and rest Home management Recreation and pastimes	136 yes/no questions	profile
NHP	Pain Physical mobility Emotional reactions Energy Social isolation Sleep	38 + 7 yes/no questions	profile

Table 1 (cont.)

Instrument:	Scales/ subscales	Response scale	Scores
MHIQ	*Physical functioning*	59 yes/no and	index
	Physical activities	more point questions	
	Mobility		
	Self care		
	Communication		
	Global physical functioning		
	Social functioning		
	General welfare		
	Family and friends support/ participation		
	Global social functioning		
	Emotional functioning		
	Self-esteem		
	Personal relationships		
	Future		
	Global emotional functioning		
WHOQOL	Overall QOL/Gen. health	100 more point questions	profile
	Physical health		
	Pain/ discomfort		
	Energy and fatigue		
	Sleep and rest		
	Psychological health		
	Positive feelings		
	Thinking, learning, memory		
	Self-esteem		
	Body image and appearance		
	Negative feelings		
	Level of independence		
	Mobility		
	Activities of daily living		
	Dependence on medication/ treatments		
	Working capacity		
	Social relationships		
	Personal relationships		
	Social support		
	Sexual activity		
	Environment		
	Physical safety		
	Home environment		
	Financial resources		
	Health and social care		
	Opportunities for acquiring new information and skills		
	Participation in and opportunities for recreation and leisure		
	Physical environment		
	Transport		
Spirituality, religion, personal beliefs			

IC = intermittent claudication, QOL = quality of life, VAS = visual analogue scale

Baseline NHP scores for claudicants were significantly worse than those of healthy controls in all domains, except Social isolation. Mobility had a significant predictive value to discriminate between patients and controls and thus was considered the underlying cause for the differences[69]. Daily activities were only partially affected, although this appeared to be influenced by comorbidity. Klevsgard et al. used the NHP in patients with varying degrees of lower limb ischaemia[68]. The claudicants included in the study scored significantly worse in all dimensions and indicated to have more problems in all areas of daily living than healthy controls. It was concluded that QOL impairments represent an interplay between the grade of ischaemia and the patient's sense of coherence. Pain, Physical mobility and Emotional reactions discriminated patients from healthy controls. The absolute walking distance did not significantly correlate with QOL. Although in contrast with other studies[43,64], the authors state that there is no linear correlation between objective measures of ischaemia and QOL, and correlations with feelings of restriction as expressed in Mobility may be stronger. The results of this study may have been affected by the fact that claudicants with other diseases restricting the walking capacity were excluded.

Barletta et al. assessed QOL in a selected group of patients with IC using the MHIQ and compared the results with laboratory exercise performance[74]. All patients with coronary or cerebrovascular disease, and other medical problems limiting exercise capacity or known to affect QOL were excluded. In comparison with matched healthy persons, a reduction in General health with significantly lower scores for Physical, Social and Emotional function was found, which is concordant with the MHIQ results of Ponte et al.[75]. Beside a small, but significant relationship between the MWD and the scores on Physical function, QOL impairments did not correlate with treadmill performance. In patients over 70 years, functioning deteriorated on all domains with ageing. Retired patients scored significantly worse than working patients, except for Emotional function.

In a study using a reduced version of the WHOQOL-100, patients with IC evaluated their QOL significantly worse than healthy controls with regard to overall QOL and physical aspects like Pain, Energy, Mobility, Activities of daily living, and Working capacity[94]. In addition, patients experienced more negative feelings and indicated to feel dependent on medication and treatments. Increasing IC only affected Mobility. Comorbidity appeared to have an important predictive value for the QOL in patients with IC[95].

In summary, although the multitude of instruments prevent a clear view on disease impact, all instruments show a broad disease impact on QOL in patients with IC. The correlation between objective parameters of IC and QOL is inconsistent. The correlation may be absent[68], too low to be predictive[5], or significant in relation to mobility[94], physical functioning[45,74], or a range of domains[43,64]. This variability may be due to differences in the sensitivity of the measures to detect meaningful changes with increasing IC, and to variations in study design, selection criteria, and characteristics of the measures.

TREATMENT EFFECTS ON QUALITY OF LIFE IN PATIENTS WITH INTERMITTENT CLAUDICATION

Conservative treatment

Regensteiner et al.[32] examined functional status in selected claudicants distributed over three regimens: supervised treadmill exercise, strength training, and a non-exercise control group. Assessments were performed with the WIQ, the PAD-PAR, the Vitalog activity monitor[100], and the Medical Outcome Study SF-20[101,102]. After 12 weeks of treadmill exercise, PAD-PAR and Vitalog scores as well as Physical functioning improved, ABPI remained unchanged. These gains were maintained at 24 weeks, and paralleled an increased treadmill walking time and improved WIQ scores for walking distance and claudication pain. Supervised treadmill training appeared to be more effective than the other regimens.

Patterson et al. tested the effectiveness of a 12 weeks supervised or home-based exercise program, using the SF-36 as a QOL measure[46]. Supervised programs provided better walking results. The scores for the physical domains of the SF-36 improved equally for both regimens. The authors conclude that a supervised program results in optimal walking benefits, but a structured home-based program provides similar functional improvements and may be a satisfactory alternative for patients with lesser walking requirements. The QOL benefits in the home exercise group are in contrast with absent[44] or minimal improvement[65,103], or even a deterioration[47] as measured with the SF-36 in patients that had been treated conservatively for comparison with patients treated with PTA and reconstructive surgery. As an explanation, the authors suggest that a high degree of interaction with health care providers in the home exercise group might be responsible for the comparable outcome in the two groups.

In a study among older claudicants Gardner et al. compared the effects of exercise rehabilitation with usual care control[104]. Treadmill performance and calf blood flow improved significantly in the exercise group. The authors concluded that the concurrent improvements in accelerometer derived physical activity in the community enabled patients to become more functionally independent. However, self-reported walking ability as measured with the WIQ and SF-36 measured QOL failed to confirm this conclusion from a patient's point of view. Using a less intensive exercise maintenance program, the gains in ambulatory function and physical activity sustained for 12 months[105]. Nevertheless, WIQ scores remained unchanged, which may be explained by the limited statistical power of the study to detect changes in self-reported walking ability. Alternatively, the authors suggest that improved treadmill walking might not translate into improved perceived walking in the community setting.

In summary, there are some indications that a supervised exercise program may produce improvements in functional status and the physical aspects of QOL. The relatively small size of the patient groups demands a reserved attitude towards the interpretation of these results.

Pharmacological treatment

Clinical trials with a variety of drugs have shown improvements in treadmill walking. In some of these studies, QOL effects have been assessed, but the patients' perception of clinical improvements are inconsistent. Since pharmacological treatment for IC is not widely accepted, these studies will not be reviewed.

Invasive treatment

Most studies on the effects of invasive therapy with respect to QOL in patients with IC were published when PTA promised to become the first treatment option. Using the SF-36, Currie et al. showed a significant improvement in Physical functioning and Pain, three months after PTA[44]. The improvements were less explicit in women and elderly, and were unrelated to changes in ABPI. These results were confirmed by Pell et al. after PTA and surgical reconstruction for IC over a six months follow-up period[47].

Feinglass et al. demonstrated that after a mean follow-up of 19 months significant improvements in ABPI after successful PTA or bypass surgery translated into improved SF-36 Physical functioning and Pain, and WIQ walking distance scores[103].

In a prospective randomised study, originally designed for the comparison of primary or selective stent placement in iliac arteries, an immediate and significant improvement was reported in all RAND-36 (which is practically equivalent to the SF-36) domains, especially the physical domains, and the TTO-derived Euroqol index[6,50]. However, the scores after revascularisation did not reach the level of the general population. Except for General health perception, there was no significant decrease in QOL scores to baseline values during two years follow-up, although there was a trend. The correlation between QOL scores and haemodynamic data was poor.

In another prospective study, QOL was assessed with the SF-36 and the global Euroqol indices before, and one, three, and six months after PTA[51]. An immediate improvement in the SF-36 domains Physical functioning, Role physical, Pain, Vitality, Social functioning, and Mental health was found, with a trend to decline in most of the domains during the short follow-up. The global Euroqol indices showed the same pattern. In 20 to 30% of the patients there was no change, or even a deterioration in claudication category or ABPI. During follow-up, a majority of patients was unable to complete treadmill testing because of comorbidity, contralateral, or residual ipsilateral IC. Nevertheless, the authors conclude that PTA improves QOL, justifying its use in the treatment of patients with IC. The same authors reported similar QOL effects after successful PTA in claudicants, stratified for different types of arterial lesions[49]. Subgroup analysis demonstrated that only patients with a single iliac lesion enjoyed QOL levels similar to those of a healthy, age-matched population, one year after successful PTA. The deterioration of the SF-36 domain General health perception in most of the patient groups was in contrast with observed improvements in other domains as well as the Euroqol indices. The residual QOL limitations, despite benefits with regard to walking distances and ABPI, were considered to be

caused by age, comorbidity, residual, and recurrent IC. Admitting that only about 10% of the claudicants have a lesion amenable to PTA and that only a subgroup may enjoy QOL benefits, the authors' claim to have provided "evidence on which to base the medicine" for the treatment of patients with IC seems overenthusiastic.

Six weeks after successful PTA for IC, Cook et al. demonstrated significant better walking distances as measured with the WIQ, and concomitant improvements in all domains of the Euroqol, except for Self care which could not be improved because of high pre-treatment scores[58]. The walking benefits and QOL effects sustained for one year at the post-PTA level, but the patients' general perception of QOL had declined[59]. It was assumed that increasing comorbidity, revelation of other impairments because of improved walking, and higher expectations associated with increased activity might be an explanation for these divergent findings. The authors suggested that the Euroqol is adequate in assessing QOL in the short term, but results should be considered with care in the long run.

Taft et al. evaluated QOL in patients with IC using a battery of measures, incorporating the SIP[65]. After 12 months, invasively treated patients showed significant improvements in walking ability and haemodynamic measures, whereas there were no objective improvements in patients that had been randomised to exercise training or observation[106]. Compared with baseline, invasively treated patients improved on the IC-specific SIP scale, Ambulation, Sleep and rest, and Recreation and pastimes, whilst only the latter improved in the exercise group and no QOL improvements were recorded in the control group. Walking ability and clinical indicators remained stable, and there was no significant deterioration of QOL in untreated patients, illustrating the benign course of IC. In general, effect sizes were small to moderate, and levels of physical dysfunction after treatment remained considerably higher than those of a healthy reference group. This finding is in concordance with the results of the Dutch Iliac Stent Trial[6], but contrasts with the findings by Chetter et al.[49] for unilateral claudicants with an isolated iliac lesion. The authors suggest that IC is only one expression of PAOD and comorbidity might contribute to the disappointing results. It was concluded that the level of evidence supporting invasive therapy is modest.

In an important and frequently quoted randomised controlled trial of PTA versus conventional medical treatment for IC, QOL was assessed with the NHP[70]. Only 10% of the claudicants could be randomised for either treatment. After six months, patients in the PTA group had longer walking distances, a higher ABPI, less occluded or stenosed arterial segments, and lower NHP pain scores. It was concluded that PTA produced better short-term improvements in walking and QOL than medical treatment alone, and was associated with less disease progression. At two years follow-up, despite more patent and less severely stenosed arterial segments in the PTA group, there were no statistically significant differences in walking distance, ABPI, or QOL between the two treatment groups[71]. The authors' conclusion that less extensive disease does not translate into improved walking or a better QOL stresses the gap between patient values and clinical observations.

In a study on QOL effects after successful intervention for lower limb ischaemia, claudicants scored significantly better in all NHP dimensions and all but one of the areas of daily living, six months after PTA or surgery compared with baseline[72]. For some of the dimensions, scores even equalled those of healthy controls. At 12 months, these results sustained for all dimensions that were not normal at baseline[73]. A high ABPI and a high sense of coherence were significantly associated with better QOL. Surprisingly, some improvements were also observed after haemodynamically unsuccessful revascularisation. The authors suggest that in addition to a possible placebo effect of PTA, this finding may be explained by the patients' need for greater support and complementary care in those areas that are responsible for their lower QOL.
In summary, invasive therapy may improve the walking capacity, with beneficial effects for functional status and those aspects of QOL that are of particular importance for patients with IC, for a limited period after the intervention. However, QOL levels after successful treatment hardly ever approach those of healthy contemporaries. At the moment, there are no convincing data to prove long-term QOL benefits of invasive therapy for IC. Better walking[46] or improvements in clinical indicators[49] that do not translate into QOL benefits, and QOL improvements after haemodynamically unsuccessful procedures[72] seem to detract from the importance of the walking problem for QOL in these patients.

DISCUSSION

IC is one of the stages of PAOD caused by atherosclerosis, a systemic, progressive, and incurable disease. Therefore, symptomatic relief of complaints is the goal of treatment. If a patient cannot be offered more than palliation and has to accept certain impairments, the impact of disease and comorbidity on QOL are pivotal for treatment strategies. Traditionally, treatment effects have been evaluated in terms of changes in ABPI, treadmill performance, and patency of vessels. Since relief of complaints is most important in IC, treatment modalities and their outcomes should primarily be evaluated in view of the patient's perception of health and QOL instead of being judged by technical possibilities and clinical success. In other words, treatment should focus on the patient that presents with IC as an expression of atherosclerosis rather than on the walking distance or the ABPI. The traditional parameters for rating disease severity and assessing treatment effects in IC have not been developed for these purposes.
There are many reports addressing the relevance of QOL for the evaluation of patients with IC. The most important obstruction for understanding and comparing study results is the liberal use of the term "QOL" for different concepts. Most of these concepts and their measures have been designed to assess the impact of disease on physical performance or psychological and social functioning. The implicit assumption that impairments caused by a disease can be subtracted from optimal functioning to indicate the patients' QOL has important limitations. A doctor's interpretation of a patient's functional impairments as good or bad QOL is not synonymous with a patient's personal evaluation of these

impairments[43,53,107]. Such "objective" interpretation of functional impairments does not take account of the individual's ability to cope with these impairments and to adjust his or her goals in life. The dynamic balance between a person's expectations and experiences, as a way to evaluate QOL[108], may not be valued by anyone, but the individual patient[109].

The differences between instruments, size of the studies (between 29 and 555 patients), duration of follow-up (two weeks to two years), and the variability of the intervals between assessments make it difficult to interpret and generalise the study results. Treatment effects on QOL are influenced by experience, expectations, hopes, and fears concerning disease progression and the method of treatment. Besides, these variables fluctuate over time and within a disease process. For instance, during a disease process, the fear for future deterioration of symptoms may decline while a certain degree of impairment becomes acceptable. This so-called response-shift makes it difficult to compare the results of studies using different assessment moments during follow-up[110].

Only few reports on QOL and IC acknowledge atherosclerosis as a progressive disease with more organs at risk than the lower limbs. The IC-related impairments may be treated well with conservative means, or may even improve spontaneously[111-115], but cardiac and cerebrovascular events threaten the claudicant's life and will have a continued impact on QOL with ageing[116]. Moreover, most studies do not take account of the role of comorbidity for the QOL in patients with IC. In some studies, patients with comorbidity or other reasons for impaired walking are even excluded[64,68,74]. However, there are convincing data documenting the high incidence of comorbidity in patients with IC and its repercussion on QOL[2,45,95]. The exclusion of other factors than the walking impairment that may have a potential impact on QOL in patients with IC neglects the complexity of the underlying cause of IC and prevents offering treatment that may be beneficial for the patient. Disregarding the majority of patients, it seems unlikely that the results of such studies contribute to an adjustment of treatment that meets the real demands.

Compared with the traditional endpoints in vascular surgery, QOL measures may be regarded soft, impractical to use, hard to value, and difficult to interpret. So, why should it be used?

Presently, several instruments for the assessment of functional status, health status, and QOL have been validated in patients with IC. The reviewed studies have provided a rough picture of the aspects of life that are responsible for the impaired health status and QOL in patients with IC and have revealed some of the effects that may be expected from different treatment modalities. Despite the accumulated data, clinical practice is still based on objective clinical parameters. Although the gap between the traditional parameters and subjective, patient-centred outcome is increasingly recognised, the absence of reports on the clinical implementation of patient-centred outcome suggests a reserved attitude towards this development in the clinical community. If it is the aim to provide optimal care for the patient with IC as the presenting expression of atherosclerosis, this knowledge should stimulate further research into subjective outcome in these patients.

It seems unlikely that one instrument will capture all relevant information that is needed to value the impact of IC on daily life and to select optimal treatment for individual patients. Objective clinical data, an indication of the functional impairments with regard to walking, appraisal of the influence of IC and associated comorbidity on physical, psychological, and social functioning, and the evaluation of functioning by the patients themselves are complementary and may assist in an optimal work-up and choice of treatment. A set of the most relevant components of the respective measures of health status and QOL may be administered at the vascular outpatient department or by (e-) mail at home. Incorporation of subjective patient information into clinical practice should direct treatment options in a way that meets individual needs and preferences.

REFERENCES

1. Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999:12:123-137

2. Dormandy J, Heeck L, Vig S. Lower extremity arteriosclerosis as a reflection of a systemic process: Implications for concomitant coronary and carotid disease. Sem Vasc Surg 1999;12:118-122

3. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538

4. Chetter IC, Dolan P, Spark JI, Scott DJA, Kester RC. Correlating clinical indicators of lower-limb ischaemia with quality of life. Cardiovascular Surgery 1997;5:361-366

5. Bosch JL, Van der Graaf Y, Hunink MGM. Health-related quality of life after angioplasty and stent placement in patients with iliac artery occlusive disease. Circulation 1999;99:3155-3160

6. Watson CJE, Phillips D, Hands L, Collin J. Claudication distance is poorly estimated and inappropriately measured. Br J Surg 1997;84:1107-1109

7. Fraser SCA. Quality of life measurement in surgical practice. Br J Surg 1993;80:163-169

8. Golledge J, Garrat A, Greenhalgh RM, Davies AH. Patient-assessed health outcome in peripheral arterial disease. Eur J Vasc Endovasc Surg 2000;19:109-110

9. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: revising the paradigm for the 21st century. J Vasc Surg 2000;32:1239-50

10. De Vries J. Beyond health status. Construction and validation of the Dutch WHO Quality of Life assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

11. De Vries J, Van Heck GL. The World Health Organization Quality of Life assessment instrument (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

12. Chetter IC, Spark JI, Dolan P, Kester RC. QOL analysis in patients with lower limb ischaemia: Suggestions for European standardisation. Eur J Vasc Endovasc Surg 997;13:597-604

13. Trans Atlantic inter-Society Consensus (TASC) working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

14. Bowling, A. Measuring health. A review of quality of life measurement scales.

Milton Keynes: Open University Press. 1991

15. De Vries J. Quality of life assessment. In: Vingerhoets AJJN (ed.). Assessment in behavioural medicine. Hove: Brunner-Routledge, 2001

16. Bergner DK. Measurement of health status. Med Care 1985;23:696-704

17. Stoker MJ, Dunbar GC, Beaumont G. The SmithKline Beecham 'quality of life' scale: A validation and reliability study in patients with affective disorder. Quality Life Res 1992;1:385-395

18. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995; 41:1403-1409.

19. Weinstein MC, Stason WB. Foundations of cost-effectiveness analysis for health and medical practices. N Engl J Med 1977;296:716-721

20. Rosser R, Watts VC. The measurement of hospital output. Int J Epidemiol 1972;1:361-368

21. Humphreys W, Evans F, Williams T. Quality of life: Is it a practical tool in patients with vascular disease? J Cardiovasc Pharmacology 1994;23:S34-S36

22. World Health Organisation. The constitution of the WHO. WHO chronicle 1947;1:29

23. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27:S217-S232

24. Bowling A. Measuring disease. Open University Press, Buckingham, 1995

25. Regensteiner JG, Steiner JF, Panzer RJ, Hiatt WR. Evaluation of walking impairment by questionnaire in patients with peripheral arterial disease. J Vasc Biol 1990;2:142-152

26. Likert R. A technique for the measurement of attitudes, Arch Psychol 1932;140: 55

27. Fitzpatrick R, Fletcher A, Gore S, Jones D, Cox D. Quality of life measures in health care. I: Applications and issues in assessment. BMJ 1992;305:1074-1077

28. Kuyken W, Orley J, Hudelson P, Sartorius N. Quality of life assessment across cultures. Int J Ment Health 1994;23: 5-27

29. Regensteiner JG, Hargarten ME, Rutherford RB, Hiatt WR. Functional benefits from peripheral vascular bypass surgery for patients with intermittent claudication. Angiology 1993;44:1-10

30. McDermott MM, Liu K, Guralnik GM. et al. Measurement of walking endurance and walking velocity with questionnaire: Validation of the walking impairment questionnaire in men and women with peripheral arterial disease. J Vasc Surg 1998;28:1072-1081

31. Sallis JF, Haskell WL, Wood PD. et al. Physical activity assessment methodology in the five city project. Am J Epidemiol 1985;121:91-106

32. Regensteiner JG, Steiner JF, Hiatt WR. Exercise training improves functional status in patients with peripheral arterial disease (PAD). J Vasc Surg 1996;23:104-115

33. Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36) I. Conceptual frame work and item selection. Med Care 1992;30:473-484

34. Ware JE. SF-36 Health Survey: Manual & interpretation guide. Boston, MA: The Health Institute, New England Medical Center;1993

35. The Euroqol group. Euroqol- A new facility for the measurement of health related quality of life. Health Policy 1990;16:199-208

36. Bergner M, Bobbitt RA, Kressel S. et al. The Sickness Impact Profile: Conceptual foundation and methodology for the development of a health status measure. Int J Health Serv 1976;6:393-415

37. Bergner M, Bobbit RA, Carter WB, Gilson BS. The sickness impact profile: Development and final revision of a health status measure. Med Care 1981;21 (8):787-805

38. Hunt SM, McKenna SP, McEwen J. The Nottingham Health Profile. Users Manual. Revised edition, 1986

39. Chambers LW. The McMaster Health Index Questionnaire (MHIQ): Methodologic documentation and report of second generation of investigations. Department of clinical epidemiology and biostatistics, McMaster University, Hamilton, Ontario, 1982

40. Bowling A. Measuring disease: A review of disease-specific quality of life measurement scales. Buckingham: Open University Press;1985

41. Chetter IC, Spark JI, Dolan P, Kester RC. QOL analysis in patients with lower limb ischaemia: Suggestions for European standardisation. Eur J Vasc Endovasc Surg 1997;13:597-604

42. Schneider JR, McHorney CA, Malenka DJ, McDaniel M, Walsh DB, Cronenwett JL. Functional health and well-being in patients with severe atherosclerotic peripheral vascular disease. Ann Vasc Surg 1993;7:419-428

43. Pell JP. Impact of intermittent claudication on QOL. Eur J Vasc Endovasc Surg 1995;9:469-472

44. Currie IC, Wilson YG, Baird RN, Lamont PM. Treatment of intermittent claudication: The impact on quality of life. Eur J Vasc Endovasc Surg 1995;10:356-361

45. Feinglass J, McCarthy WJ, Slavensky R, Manheim L, Martin GJ and the Chicago Claudication Outcomes Research Group. Effect of lower extremity blood pressure on physical functioning in patients who have intermittent claudication. J Vasc Surg 1996;24:503-512

46. Patterson RB, Pinto B, Marcus B, Colucci A, Braun T, Roberts M. Value of a supervised exercise program for the therapy of arterial claudication. J Vasc Surg 1997 Feb;25(2):312-18

47. Pell JP, Lee AJ. Impact of angioplasty and arterial reconstructive surgery on the quality of life of claudicants. The Scottish Vascular Audit Group. Scott Med J 1997;42:47-48

48. Bartman BA, Rosen MJ, Bradham DD, Weissman J, Hochberg M, Revicki DA. Relationship between health status and utility measures in older claudicants. Qual Life Res 1998 Jan;7(1):67-73

49. Chetter IC, Spark JI, Kent PJ, Berridge DC, Scott DJA, Kester RC. Percutaneous transluminal angioplasty for intermittent claudication: Evidence on which to base the medicine. Eur J Vasc Endovasc Surg 1998;16:477-484

50. Tetteroo E, Van der Graaf Y, Bosch JL. et al. Randomised comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac-artery occlusive disease. Dutch Iliac Stent Trial Study Group. Lancet 1998;351:1153-1159

51. Chetter IC, Sparks JI, Scott JA, Kester RC. Does angioplasty improve the quality of life for claudicants? A prospective study. Ann Vasc Surg 1999;13:93-103

52. Holtzman J, Caldwell M, Walvatne C, Kane R. Long term functional status and quality of life after lower extremity revascularization. J Vasc Surg 1999;29:395-402

53. Hicken GJ, Lossing AG, Ameli FM. Assessment of generic health-related quality of life in patients with intermittent claudication. Eur J Vasc Endovasc Surg 2000;20:336-341

54. Dolan P. Modeling valuations for Euroqol health states. Med Care 1997;35:503-520

55. Kind P. Measuring health status in the community: a comparison of methods. J Epidemiol Commun Health 1994;48:86-91

56. Brazier J, Jones N, Kind P. Testing the validity of the Euroqol and comparing it with the SF-36 health survey questionnaire. Qual Life Res 1993;2:169-180

57. Humphreys W, Evans F, Williams T. Quality of life: Is it a practical tool in patients with vascular disease? J Cardiovasc pharmacology 1994;23:S34-S36

58. Cook TA, O'Regan M, Galland RB. QOL following PTA for claudication. Eur J Vasc Endovasc Surg 1996;11:191-194

59. Cook TA, Galland RB. Quality of life changes after angioplasty for claudication: medium-term results affected by comorbid conditions. Cardiovasc Surg 1997:5:424-426

60. Chetter IC, Dolan P, Spark JI, Scott DJA, Kester RC. Correlating clinical indicators of lower limb ischaemia with quality of life. Cardiovasc Surg 1997;5:361-366

61. De Vries SO, Kuipers WD, Hunink MG. Intermittent claudication: symptom severity versus health values. J Vasc Surg 1998;27:422-430

62. Bosch JL, Hunink MG. Comparison of the Health Utilities Index Mark 3 (HUI3) and the EuroQol EQ-5D in patients treated for intermittent claudication. Qual Life Res 2000;9(6):591-601

63. McKenzie CR, Charlson ME, DiGroia D et al. Can the Sickness Impact Profile measure change? An example of scale assessment. J Chron Dis 1986;39:429-438

64. Arfvidsson B, Karlsson J, Dahllof A-G, Lundholm K, Sullivan M. The impact of intermittent claudication on quality of life evaluated by the Sickness Impact Profile technique. Eur J Clin Invest 1993;23:741-745

65. Taft C, Karlsson J, Gelin J. et al. Treatment efficacy of intermittent claudication by invasive therapy, supervised physical exercise training compared to no treatment in unselected randomised patients II: One year results of health-related quality of life. Eur J Vasc Endovasc Surg 2001;22:114-123

66. McEwen J. The Nottingham Health Profile. In: Walker SR, Rosser RM. Quality of life assessment: Key issues in the 1990's. Kluwer Academic Publishers, Lancaster, 1993

67. Kind P, Carr-Hill R. The Nottingham Health Profile; a useful tool for epidemiologists. Soc Sci Med 1987;25:905-910

68. Klevsgard R, Hallberg IR, Risberg B, Thomsen MB. Quality of life associated with varying degrees of chronic lower limb ischaemia: Comparison with a healthy sample. Eur J Vasc Endovasc Surg 1999;17:319-325

69. Khaira HS, Hanger R, Shearman CP. QOL in patients with intermittent claudication. Eur J Vasc Endovasc Surg 1996;11:65-69

70. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Randomised controlled trial of percutaneous transluminal angioplasty for intermittent claudication. Eur J Vasc Endovasc Surg 1996;12:167-172

71. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Is intermittent claudication improved by PTA? A randomised controlled trial. J Vasc Surg 1997;26:551-557

72. Klevsgard R, Hallberg IR, Risberg B, Thomsen MB. The effect of successful intervention on quality of life in patients with varying degrees of lower limb ischaemia. Eur J Vasc Endovasc Surg 2000;19:238-245

73. Klevsgard R, Risberg BO, Thomsen MB, Hallberg IR. A 1-year follow-up quality of life study after hemodynamically successful or unsuccessful surgical revascularization of lower limb ischemia. J Vasc Surg 2001;33:114-122

74. Barletta G, Perna S, Sabba C, Catalano A, O'Boyle C, Brevetti G. QOL in pts with intermittent claudication: relationship with laboratory exercise performance. Vasc Medicine 1996;1:3-7

75. Ponte E, Cattinelli S. QOL in a group of patients with intermittent claudication. Angiology 1996;47:247-251

76. Brevetti G, Perna S, Sabba C, Martone VD, Di Iorio A, Barletta G. Effect of propionyl-L-carnitine on quality of life in intermittent claudication. Am J Cardiol 1997 Mar 15;79(6):777-80

77. Marquis P, Fayol C, McCarthy C, Fiessinger JN. Measurement of quality of life in intermittent claudication. Clinical validation of a questionnaire. Presse Med 1994;23(28):1288-92

78. Bullinger M, Cachovan M, Creutzig A. et al. Development of an illness-specific instrument for assessment of quality of life in patients with arterial occlusive disease (Peripheral Arterial Occlusive Disease 86 Questionnaire). Vasa 1996;25(1):32-40

79. Finger T, Kirchberger I, Dietze S. et al. Assessing the quality of life of patients with intermittent claudication: psychometric properties of the claudication scale (CLAU-S). Qual Life Res 1995;4:122-127

80. Spengel FA, Lehert P, Dietze S. A statistical consideration of CLAU-S: A disease specific questionnaire for the assessment of quality of life in patients with intermittent claudication. Vasa 1998 Nov;27(4):253

81. Lehert P. Quality-of-life assessment in comparative therapeutic trials and causal structure considerations in peripheral occlusive arterial disease. Pharmacoeconomics 2001;19(2):121-30

82. Marquis P, Comte S, Lehert P. International validation of the CLAU-S quality-of-life questionnaire for use in patients with intermittent claudication. Pharmacoeconomics 2001;19(6):667-677

83. Morgan MB, Crayford T, Murrin B, Fraser SC. Developing the Vascular Quality of Life Questionnaire: A new disease-specific quality of life measure for use in lower limb ischemia. J Vasc Surg 2001 Apr;33(4):679-87

84. Silvestro A, Bacchieri A, Bucur R. et al. A new questionnaire for assessing the quality of life of patients with intermittent claudication. Minerva Cardioangiol 2000 Dec;48(12):455-65

85. Creutzig A, Bullinger M, Cachovan M. et al. Improvement in the quality of life after i.v. PGE1 therapy for intermittent claudication. Vasa 1997 May;26(2):122-7

86. Marquis P, Lecasble M, Passa P. Quality of life of patient with peripheral arterial obliterative disease treated with ifenprodil tartrate. Results of an ARTEMIS study. Drugs 1998;56 Suppl 3:37-48

87. Spengel F, Brown TM, Poth J, Lehert P. Naftidrofuryl can enhance the quality of life in patients with intermittent claudication. Vasa 1999 Aug;28(3):207-12

88. D'Hooge D, Lehert P, Clement DL. Naftidrofuryl in quality of life (NIQOL). A Belgian Study. Int Angiol 2001 Dec;20(4):288-294

89. Brevetti G, Diehm C, Lambert D. European multicenter study on propionyl-L-carnitine in intermittent claudication. J Am Coll Cardiol 1999 Nov 1;34(5):1618-24

90. Muller-Buhl U, Kirchberger I, Wiesemann A. Relevance of claudication pain distance in patients with peripheral arterial occlusive disease. Vasa 1999;28:25-29

91. O'Carroll RE, Smith K, Couston M, Cossar JA, Hayes PC. A comparison of the WHOQOL-100 and the WHOQOL-BREF in detecting change in quality of life following liver transplantation. Qual Life Res 2000 Feb;9(1):121-4

92. De Vries J, Drent M, Van Heck GL, Wouters EFM. Quality of life in sarcoidosis: A comparison between members of a patient organisation and a random sample. Sarcoidosis Vasc Diffuse Lung Dis 1998;15:183-188

93. Wirnsberger RM, De Vries J, Brteler MHM, Van Heck GL, Wouters EFM, Drent M. Evaluation of quality of life of sarcoidosis patients. Resp Med 1998;92:750-756

94. Breek JC, Hamming JF, De Vries J, Aquarius AEAM, Van Berge Henegouwen DP. Quality of life in patients with intermittent claudication using the World Health Organisation (WHO) Questionnaire. Eur J Vasc Endovasc Surg 2001;21:118-122

95. Breek JC, Hamming JF, De Vries J, Van Berge Henegouwen DP, Van Heck GL. The impact of walking impairment, cardiovascular risk factors, and comorbidity on quality of life in patients with intermittent claudication. J Vasc Surg 2002;36:94-99

96. Joyce CRB. Health status and quality of life: Which matters to the patient? J Cardiovasc Pharmacol 1994;23(suppl.3):S26-S33

97. Golledge J, Garrat A, Greenhalgh RM, Davies AH. Patient-assessed health outcome in peripheral arterial disease. Eur J Vasc Endovasc Surg 2000;19:109-110

98. Beattie DK, Golledge J, Greenhalgh RM, Davies AH. QOL assessment in vascular disease: Towards a consensus. Eur J Vasc Endovasc Surg 1997;13:9-13

99. Bosch JL, Hunink MGM. The relationship between descriptive and valuational quality of life measures in patients with intermittent claudication. Med Decis Making 1996;16:217-225

100. Mueller JK, Gossard D, Adams FR, et al. Assessment of prescribed increases in physical activity: application of a new method for microprocessor analysis of heart rate. Am J Cardiol 1986;57:441-445

101. Tarlov AR, Ware JE, Greenfield S, Nelson EC, Perrin E, Zubkoff M. The medical outcome study. An application of methods for monitoring the results of medical care. JAMA 1989;262:925-930

102. Stewart AL, Greenfield S, Hays RD. et al. Functional status and well-being of patients with chronic conditions: results from the medical outcome study. JAMA 1989;262:907-913

103. Feinglass J, McCarthy WJ, Slavensky R, Manheim LM, Martin GJ. Functional status and walking ability after lower extremity bypass grafting or angioplasty for intermittent claudication: results from a prospective outcomes study. J Vasc Surg 2000;31:93-103

104. Gardner AW, Katzel LI, Sorkin JD. et al. Exercise rehabilitation improves functional outcomes and peripheral circulation in patients with intermittent claudication: a randomized controlled trial. J Am Geriatr Soc 2001;49(6):755-62

105. Gardner AW, Katzel LI, Sorkin JD, Goldberg AP. Effects of long-term exercise rehabilitation on claudication distances in patients with peripheral arterial disease: a randomized controlled trial. J Cardiopulm Rehabil 2002 May-Jun;22(3):192-8

106. Gelin J, Jivegard L, Taft C. et al. Treatment efficacy of intermittent claudication by surgical intervention, supervised physical exercise training compared to no treatment in unselected randomised patients I: One year results of functional and physiological improvements. Eur J Vasc Endovasc Surg 2001;22:107-113

107. Slevin ML, Plant H, Lynch D, Drinkwater J, Gregory WM. Who should measure quality of life, the doctor or the patient? Br J Canc 1988;57:109-112

108. Calman KC. Quality of life in cancer patients- a hypothesis. J Med Ethics 1984;10:124-127

109. Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of-life measurements. JAMA 1994;272:619-626

110. Carr AJ, Gibson B, Robinson PG. Measuring quality of life. Is quality of life determined by expectations or experience? BMJ 2001;322:1240-1243

111.Creasy TS, McMillan PJ, Fletcher EWL, Collin J, Morris PJ. Is percutaneous transluminal angioplasty better than exercise for claudication? Preliminary results from a prospective randomised trial. Eur J Vasc Surg 1990;4:135-140

112.Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain. A meta-analysis. JAMA 1995;274:975-980

113.Perkins JMT, Collin J, Creasy TS, Fletcher EWL, Morris PJ. Exercise training versus angioplasty for stable claudication. Long and medium term results of a prospective randomised trial. Eur J Vasc Surg 1996;11:409-413

114.Robeer, GG, Brandsma JW, Van den Heuvel SP, Smit B, Oostendorp RA, Wittens CH. Exercise therapy for intermittent claudication: A review of the quality of randomised clinical trials and evaluation of predictive factors. Eur J Vasc Endovasc Surg 1998;15:36-43

115.Leng GC, Fowler B, Ernst E. Exercise for intermittent claudication. Cochrane Database Syst Rev 2000;(2):CD000990

116.Dormandy J, Heeck L, Vig S. Intermittent claudication: Underrated risks. Sem Vasc Surg 1999;12:96-108

CHAPTER 3

MEASURING QUALITY OF LIFE AND HEALTH STATUS IN PATIENTS WITH PERIPHERAL ARTERIAL OCCLUSIVE DISEASE OF THE LOWER LIMBS

A PILOT STUDY

INTRODUCTION

The impact of vascular disease on quality of life (QOL) is recommended as an independent outcome measure and a guideline for treatment policy[1,2]. However, most studies that claim to assess QOL actually concern measurements of health status. QOL and health status are related but distinct concepts of which the similarities and differences will be discussed in detail in chapter 4. Health status, also known as health-related QOL, assesses the influence of disease on physical, social, and emotional functioning; it measures factual restrictions in functioning[3,4]. QOL, as defined by the World Health Organisation (WHO)[5], is a broader concept comprising the personal *evaluation* of functioning with regard to physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment.
Health status has been measured in a number of studies concerning intermittent claudication (IC) and chronic critical ischaemia of the lower limbs[6-11], while QOL, as defined by the WHO, has not been studied in vascular disease before. With the purpose to conduct a study on QOL, the WHO QOL assessment instrument-100 (WHOQOL-100)[12] was chosen, because it corresponds best with the subjective character of the WHO definition of QOL. Until now, the WHOQOL-100 has not been used in patients with vascular disease. Therefore, it was decided to perform a pilot study on the appropriateness of the instrument for the assessment of QOL in patients with peripheral arterial occlusive disease (PAOD). To compare the results with a widely accepted and frequently used health status measure in patients with PAOD, the RAND-36[13,14] was also administered. Because the WHOQOL-100 was expected to be too laborious for an elderly group of patients, the second goal of the study was to shorten the questionnaire to reduce patient burden. Finally, the actual process of completing the questionnaires was studied.

MATERIAL AND METHODS

Patients

Twenty-two patients presenting with various degrees of PAOD, who were referred to the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands were asked to participate in this pilot study. The sample consisted of 14 men and 8 women with a mean age of 71 years (range: 49-88). The degree of ischaemia was recorded according to a slightly modified version of the recommended standards for reports dealing with lower extremity ischaemia as defined by the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCS)[15] (Table 1). The medico-ethical commission of the St. Elisabeth Hospital approved the study. All patients provided written, informed consent prior to participation.

Table 1
Degree of ischaemia according to the SVS/ISCVS[15] in 22 patients with peripheral arterial occlusive disease of the lower limbs

Mild claudication	1
Moderate claudication	7
Severe claudication	5
Rest pain	1
Tissue loss	8

Mild claudication: Completes modified treadmill exercise*; ankle pressure after exercise > 50 mm Hg, but at least 20 mm Hg lower than resting value. Moderate claudication: Between mild and severe. Severe claudication: Cannot complete modified treadmill exercise and ankle pressure after exercise < 50 mm Hg. Ischaemic rest pain: resting ankle pressure <40 mm Hg, flat or barely pulsatile ankle or metatarsal pulse volume recording (PVR). Toe pressure <30 mm Hg. Tissue loss: resting ankle pressure <30 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; toe pressure <40 mm Hg. * 3,5 km/h on a 5% incline with a maximum of 1000 m.

Instruments

The WHOQOL-100 is a generic, multidimensional, self-report QOL measure that is easy to score. It has good psychometric properties[16,17]. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world[5]. It consists of 100 items assessing 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, Spirituality/religion/personal beliefs) and a generic evaluative facet (Overall QOL and general health)[18]. Each facet is represented by four items. The response scales are 5-point Likert scales[19]. Scores on each facet and domain can range from 4 to 20.

The RAND-36, which is practically identical to the Medical Outcome Study/Short Form-36 (SF-36)[20], was chosen as a health status measure because of its proven applicability in PAOD. The use of this instrument meets the recommended standardisation of reporting health status in vascular disease[21-23]. The RAND-36 is a 36-item generic health status measure. It assesses health in eight domains: Physical functioning, Social functioning, Limitations in usual role activities due to physical problems (Role physical), Limitations in usual role activities due to emotional problems (Role emotional), Mental health, Vitality, Bodily pain, and General health perception. In addition, Health changes over the last year are assessed. Beside scores for each subscale the testing yields a composite health status score on a scale from 0 to 100. The RAND-36 is short and sensitive to intervening illness, for instance among the relatively healthy elderly. It has a good reliability and validity[24].

Procedure

Once the diagnosis PAOD was made, based on history, physical examination, ankle blood pressure and, in case of IC, treadmill tests, the patient was asked to participate in our QOL/health status

research project. All patients completed the WHOQOL-100 and RAND-36. The participants were observed by a research assistant from the University Department of Psychology and Health in order to detect problems and external factors that could influence completion of the questionnaires in a practical and/or substantial way. The assistant was allowed to explain questions in a standardised way to the participants when necessary.

Statistics

The WHOQOL-100 and RAND-36 scores are presented in terms of means and standard deviations. One sample T-tests were used for comparing patients with values of a reference group. Probability values of less than 0.05 were considered to be statistically significant. Two measures of response distribution were used. Kurtosis, which describes the peakedness of the distribution (<0.00) and skewness, which means that the length of one of the tails of the distribution, relative to the central section, is disproportionate to the other (between –0.50 and 0.50)[25]. Internal consistency, a measure for the reliability of the instrument, was calculated using Cronbach's alpha coefficients[26].

RESULTS

QOL in PAOD patients appeared mainly affected in the domains Physical health and Level of independence (Table 2).

Cronbach's alphas ranged from 0.63 for the social domain to 0.88 for the spiritual domain. At the facet level, Cronbach's alphas ranged between 0.44 for Health and social care and 0.94 for Working capacity (Table 3).

The response distribution of the WHOQOL-100 facets Energy and fatigue, Thinking, learning, memory and concentration, Bodily image and appearance, Mobility, Activities of daily living, Social support, Physical safety and security, Financial resources, Opportunities for acquiring new information and skills, Physical environment, and Transport, as well as the Spiritual domain were too small and/or skewed (Table 4, Fig.1).

In the completion of the WHOQOL-100 some specific problems were encountered. Questions on work were regarded not applicable by many elderly patients, although the instruction that goes with these questions stated that the word "work" meant "work you feel take up a major part of your time and energy". In addition, the questions about physical safety appeared to be too vague. A question belonging to the facet Physical environment, "How healthy is your physical environment?" (Facet 22.1, see Appendix I), was not clear to the patients. It seemed equivocal whether the question referred to the health condition of persons in the patient's environment or to the quality of the environment itself (e.g. pollution, noise). Finally, questions on social services (Facet 19, see Appendix I) were interpreted as getting welfare, in the sense of government support, and were thus considered not applicable to the personal situation.

Table 2
WHOQOL-100 scores of 22 patients with peripheral arterial occlusive disease and of a reference group of elderly persons*

	Elderly persons		Patients		Significance
	m	sd	m	sd	
-Overall QOL and general health	15.6	2.6	13.7	2.9	P < .002
Physical health	14.5	2.6	12.4	3.0	P < .001
- Pain and discomfort	10.3	3.2	13.2	3.3	P < .001
- Energy and fatigue	14.5	3.0	11.4	3.3	P < .001
- Sleep and rest	15.2	3.7	14.9	4.6	ns
Psychological health	14.9	1.8	14.3	2.4	ns
- Positive feelings	14.0	2.2	12.9	2.7	P < .038
- Thinking, learning, memory, concentration	14.6	2.2	14.2	3.3	ns
- Self-esteem	14.5	2.1	13.7	2.8	ns
- Body image and appearance	17.0	2.8	17.0	3.3	ns
- Negative feelings	9.4	3.0	10.3	3.3	ns
Level of independence	15.4	2.8	10.9	2.9	P < .001
- Mobility	15.3	3.2	10.5	2.7	P < .001
- Activities of daily living	15.8	3.1	11.9	3.4	P < .001
- Dependence on medication and treatments	8.9	3.3	13.8	3.3	P < .001
- Working capacity	15.5	3.3	11.1	4.3	P < .001
Social relationships	15.3	2.3	14.7	2.6	ns
- Personal relationships	16.1	2.6	15.5	2.9	ns
- Social support	15.8	3.1	15.9	3.4	ns
- Sexual activity	14.0	3.8	12.8	3.9	ns
Environment	15.7	1.7	15.2	1.9	ns
- Physical safety and security	15.5	2.4	16.0	2.2	ns
- Home environment	15.7	2.5	15.0	3.00	ns
- Financial resources	16.4	3.1	17.6	2.3	P < .032
- Health and social care	15.7	2.4	14.9	1.7	ns
- Opportunities for acquiring new information and skills	15.0	2.5	13.0	2.4	P < .001
- Participation in and opportunities for recreation/leisure	15.1	2.9	14.0	3.5	ns
- Physical environment	15.1	2.4	14.7	2.5	ns
- Transport	16.9	3.2	16.2	3.4	ns
Spirituality, religion, personal beliefs	13.7	3.5	11.2	3.5	P < .002

Note: m = mean, sd = standard deviation, ns = not significant
The scores on the facets Pain and discomfort, Negative feelings and Dependence on medication and treatments are inverse. High scores reflect low QOL. * N = 178, mean age 70 years (range 60-91 years)

Table 3
Internal consistency of the WHOQOL-100 in 22 patients with peripheral arterial occlusive disease

	Cronbach's alpha
-Overall QOL and general health	.82
Physical health	.70
- Pain and discomfort	.75
- Energy and fatigue	.80
- Sleep and rest	.87
Psychological health	.83
- Positive feelings	.81
- Thinking, learning, memory, concentration	.81
- Self-esteem	.73
- Body image and appearance	.88
- Negative feelings	.75
Level of independence	.86
- Mobility	.72
- Activities of daily living	.77
- Dependence on medication and treatments	.73
- Working capacity	.94
Social relationships	.63
- Personal relationships	.52
- Social support	.88
- Sexual activity	.80
Environment	.84
- Physical safety and security	.58
- Home environment	.77
- Financial resources	.85
- Health and social care	.44
- Opportunities for acquiring new information and skills	.65
- Participation in and opportunities for recreation/leisure	.81
- Physical environment	.46
- Transport	.70
Spirituality, religions, personal beliefs	.88

Table 4
Response distribution of the WHOQOL-100 facets and domains in 22 patients with peripheral arterial occlusive disease

	Skewness	sd	Kurtosis	sd
-Overall QOL and general health	-.13	.49	-.46	.95
Physical health	.22	.49	-.36	.95
- Pain and discomfort	-.17	.49	-.38	.95
- Energy and fatigue	.53	.49	-.44	.95
- Sleep and rest	-.29	.49	-1.62	.95
Psychological health	-.01	.49	-.35	.95
- Positive feelings	-.06	.49	-.27	.95
- Thinking, learning, memory, concentration	-.53	.49	-.58	.95
- Self-esteem	-.06	.49	-.17	.95
- Body image and appearance	-1.99	.49	5.01	.95
- Negative feelings	-.34	.49	-.61	.95
Level of independence	-.21	.49	-.69	.95
- Mobility	-.46	.50	.61	.97
- Activities of daily living	.34	.49	.04	.95
- Dependence on medication and treatments	-.09	.49	-.36	.95
- Working capacity	.05	.49	-.72	.95
Social relationships	.12	.50	-.71	.97
- Personal relationships	-.27	.50	-.81	.97
- Social support	-1.14	.50	2.04	.97
- Sexual activity	.15	.52	-.87	1.01
Environment	- .16	.50	-.04	.97
- Physical safety and security	-.40	.49	.56	.95
- Home environment	-.03	.49	-.97	.95
- Financial resources	-1.77	.50	2.82	.97
- Health and social care	-14	.50	-.70	.97
- Opportunities for acquiring new information and skills	.38	.50	.53	.97
- Participation in and opportunities for recreation/leisure	.06	.50	-1.03	.97
- Physical environment	-.16	.50	.48	.97
- Transport	-.51	.50	-.72	.97
Spirituality, religions, personal beliefs	-.64	.49	.14	.95

Criteria: Skewness between –0.50 and 0.50, kurtosis <0.00

Concerning health status, patients' scores were significantly worse for all RAND-36 domains (Table 5).

Table 5
RAND-36 scores in 22 patients with peripheral arterial occlusive disease and a reference group of elderly persons*

	Elderly persons		Patients		Significance
	m	sd	m	sd	
Physical functioning	66.7	(26.0)	40.6	(25.1)	P < .001
Social functioning	83.2	(23.7)	55.7	(34.2)	P = .001
Role physical	69.1	(42.5)	27.6	(38.1)	P < .001
Role emotional	82.9	(33.8)	58.7	(45.8)	P = .025
Mental health	75.9	(17.3)	62.5	(23.2)	P = .014
Vitality	64.2	(22.0)	47.5	(21.9)	P = .002
Bodily pain	74.8	(28.0)	44.0	(30.4)	P < .001
General health perception	60.1	(23.9)	45.9	(24.7)	P = .013

Note: m = mean, sd = standard deviation. * Dutch RAND-36 norm scores for the age group 65-75 years, N = 118

Cronbach's alphas ranged from 0.67 for Vitality to 0.92 for Bodily pain (Table 6). The RAND-36 domains Role physical and Vitality did not meet the distribution criteria (Table 7, Fig.1). The following observations were made with respect to the completion of the RAND-36. One question of the domain Physical functioning (3a, see Appendix II) asks the patient to assess his/her personal capacity to perform a number of vigorous activities such as running and sports. Patients responded that they could not answer such questions because they avoided strenuous activities due to impaired mobility and pain. In two other questions (3d and 3e, see Appendix II) the Dutch word "trap", meaning step as well as staircase is used.

Table 6
Internal consistency of the RAND-36 domains in 22 patients with PAOD

	Cronbach's alpha
Physical functioning	.88
Social functioning	.87
Role physical	.85
Role emotional	.90
Mental health	.83
Vitality	.67
Bodily pain	.92
General health perception	.82

Table 7
Response distribution of the RAND-36 domains in 22 patients with PAOD

	Skewness	sd	Kurtosis	sd
Physical functioning	-.080	.536	-1.269	1.038
Social functioning	-.221	.491	-1.312	.953
Role physical	1.172	.524	-.131	1.014
Role emotional	-.419	.501	-1.783	.972
Mental health	-.236	.491	-.905	.953
Vitality	.729	.491	.766	.953
Bodily pain	.027	.491	-.871	.953
General health perception	.299	.491	-1.003	.953

Criteria: Skewness between –0.50 and 0.50, kurtosis <0.00

Patients seemed to be confused as to what they were responding to: their ability to get up one step or climb a whole flight of stairs. The purport of two other questions of the domains Role physical (4b) and Role emotional (5b) (did you, because of physical health or emotional problems accomplished less than you would like?) seemed unclear and it was commented that these questions were too vague. Finally, statements concerning General health perception, i.e. "I seem to get sick a little easier than other people" (11a) and "I am as healthy as anybody I know" (11b) were considered difficult to answer because patients did not know whether they should take people of their own age as a point of reference or not.

From observation it appeared that patients, when they were accompanied by their partner or a relative, had the tendency to complete the questionnaires in collaboration with that person. Especially male patients tended to let their spouse complete the questionnaires for them. Middle-aged patients needed some 20 minutes for completion of both the questionnaires, whereas elderly patients needed 40 minutes or more. Reasons for this apparent difference were: visual problems, patients had forgotten their reading glasses, elderly persons needed more time to select their answers, elderly persons had more difficulty with understanding the purpose of some questions. The necessity to read questions and answers to a patient because of visual problems, raised a problem in patients hard of hearing. Furthermore, it appeared that, although demented patients were excluded from the study, an impaired short-term memory in some elderly patients made them forget the question concerning the answers they were reading. If the research assistant had to read questions, elderly patients frequently considered topics like relationships and sex as embarrassing and difficult, and consequently not applicable to them.

Figure 1
Response distribution histograms of WHOQOL-100 facets and domains and RAND-36 domains that did not meet the criteria in 22 patients with PAOD

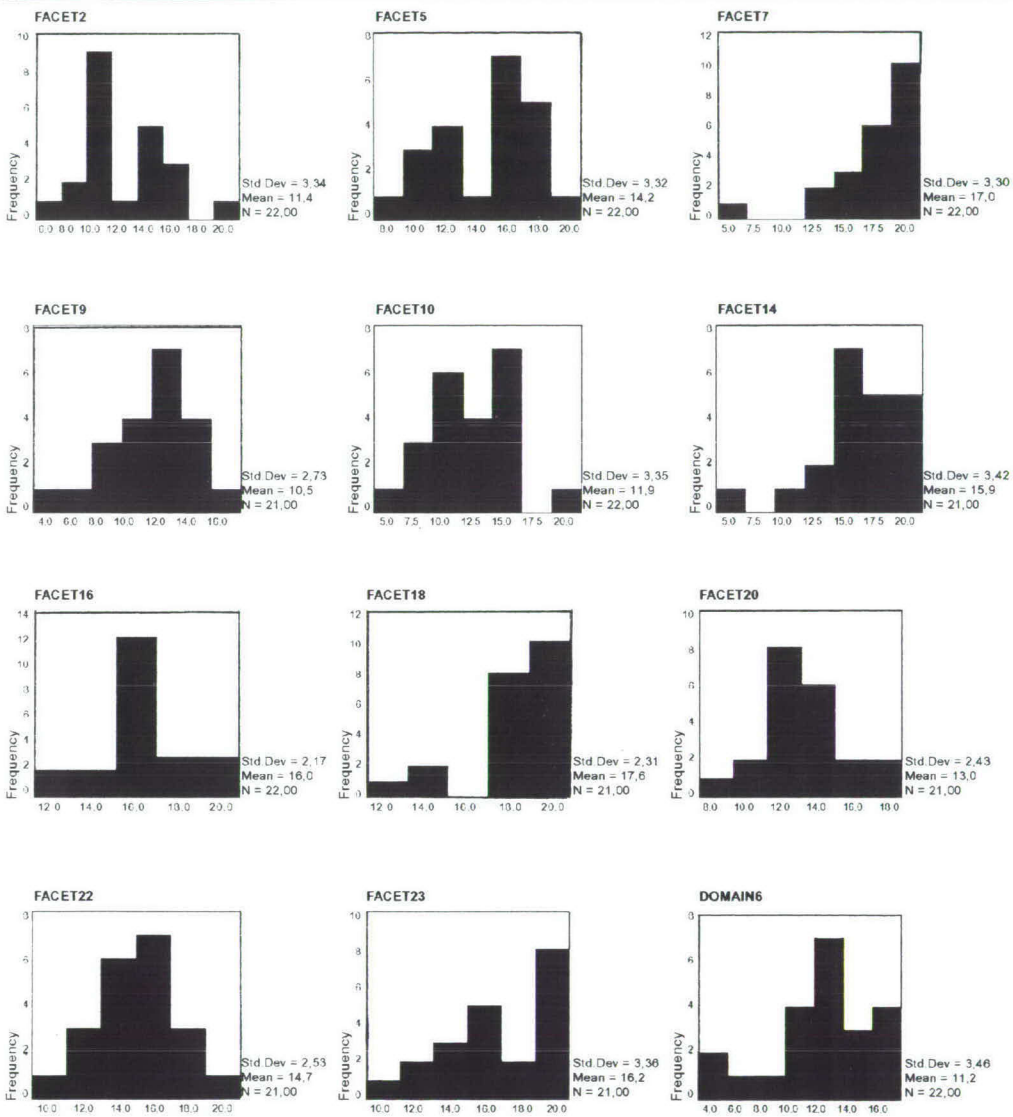
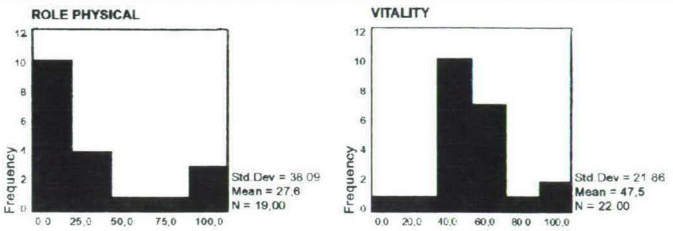


Figure 1 (cont.)



Note: Facet 2 = Pain and discomfort, Facet 5 = Thinking, learning, memory and concentration, Facet 7 = Bodily image, Facet 9 = Mobility, Facet 10 = Activities of daily living, Facet 14 = Social support, Facet 16 = Physical safety and security, Facet 18 = Financial resources, facet 20 = Opportunities for acquiring new information and skills, Facet 22 = Physical environment, Facet 23 = Transport, Domain VI = Spirituality, religion, personal beliefs

DISCUSSION

The internal consistency of the WHOQOL-100 appeared to be acceptable to good, with Cronbach's alpha's being > 0.70 for most of the facets and domains. While the WHOQOL-100 measures QOL in a broad way, only the relevant aspects for a particular patient group may contribute to a better understanding of a patient's perception of disease. In order to retain the most relevant aspects for PAOD patients, the WHOQOL-100 was reduced by means of the criteria for kurtosis and skewness, the histograms, and a comparison of scores with those of a reference group of elderly persons from the validation study of the Dutch version of the instrument[27]. As a result, we suggest not to use the facets Thinking, learning, memory, and concentration, Bodily image and appearance (both from the domain Psychological health), Social support (from the domain Social relationships), Physical safety and security, Financial resources, Availability of health and social care, and Physical environment (all from the domain Environment) and the spiritual domain in future studies on PAOD patients.

Although the facets Energy and fatigue, Mobility, Activities of daily living, and Opportunity for acquiring new information/skills neither met the response distribution criteria, they may be retained because the scores on these facets were significantly worse in PAOD patients than in the reference group. In other words, patients feel impaired on these facets and thus may improve after treatment.

The response distribution of the facet Transport only minimally deviated with respect to kurtosis. The facet was retained, also because of its expected value for persons with physical impairments.

Despite acceptable skewness and kurtosis, the facet Health and social care should be removed from the instrument in future PAOD studies, because of a low internal consistency. By eliminating the facets that do not provide additional information, the instrument can be reduced from 100 to 68 questions in PAOD studies, which is in accordance with the wish to shorten the questionnaire in

view of the observed concentration problems in elderly patients.
The value of the RAND-36 as a health status measure in patients with PAOD has been highlighted in previous studies, and has resulted in its recommended use for reporting health status in these patients. Therefore, it was decided not to adapt this measure. Apart from the fact that some questions were considered unclear, which may be solved by the presence of a research assistant, the Dutch translation of the RAND-36 appears useful.
Questionnaires with large letters and the availability of reading glasses may overcome the observed reading problems hindering the completion of the questionnaires. The tendency to complete the questionnaires together with accompanying partners or relatives, or even to leave completion entirely to them is regarded undesirable, because the perception of patients' health by others may strongly differ from the patients' own view[28].
To be sure that the completed questionnaires adequately reflect subjective QOL and patient-perceived health status, it seems essential that the questionnaires are completed by the patient alone. If questions are not well understood or cannot be remembered long enough to select an appropriate answer, a research assistant available for explanation and practical help may bring relief. If questions have to be read to the patient, a room giving privacy and a neutral attitude of the assistant are important. These practical aspects have to be taken into account, because they affect the measuring of QOL and health status and may introduce a bias in case they are ignored.
Assessing QOL in patients with chronic critical as well as non-critical ischaemia of the lower limbs may be regarded undesirable, because the patient groups may differ importantly with respect to age, life expectancy, prognosis, and degree of the handicap. Although this can be regarded as a weakness of the study, the findings may be representative for both groups, since the response distribution of the WHOQOL-100 and RAND-36 was quite similar in a homogeneous group of 18 patients with IC. However, the first aim of the study was to evaluate the appropriateness of the WHOQOL-100 for the assessment of QOL in patients with PAOD by means of parameters of internal consistency and response distribution. In order to obtain a range of answers, a broad distribution of ischaemia was required, which gave reason to incorporate both patient groups.

REFERENCES

1. Chetter IC, Scott DJA, Kester RC. An introduction to quality of life analysis: The new outcome measure in vascular surgery. Eur J Vasc Endovasc Surg 1998;15:4-6

2. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: Revising the paradigm for the 21st century. J Vasc Surg 2000;32:1239-1250

3. Bergner DK. Measurement of health status. Med Care 1985;23:696-704

4. Stoker MJ, Dunbar GC, Beaumont G. The SmithKline Beecham 'quality of life' scale: A validation and reliability study in patients with affective disorder. Quality Life Res 1992;1:385-395

5. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

6. Pell JP. Impact of intermittent claudication on quality of life. The Scottish Vascular Audit Group. Eur J Vasc Endovasc Surg 1995;9:469-472

7. Currie IC, Wilson IG, Baird RN, Lamont PM. Treatment of intermittent claudication: The impact on quality of life. Eur J Vasc Endovasc Surg 1995;10:356-36

8. Chetter IC, Spark JI, Kent PJ, Berridge DC, Scott DJA, Kester RC. Percutaneous transluminal angioplasty for intermittent claudication: Evidence on which to base the medicine. Eur J Vasc Endovasc Surg 1998;16:477-484

9. Chetter IC, Spark JI, Scott DJA, Kester RC. Does angioplasty improve the quality of life for claudicants? A prospective study. Ann Vasc Surg 1999;13:93-103

10. Chetter IC, Spark JI, Scot DJA, Kent PJ, Berridge DC, Kester RC. Prospective analysis of quality of life in patients following infrainguinal reconstruction for chronic critical ischaemia. Br J Surg 1998;85:951-955

11. Duggan MM, Woodson J, Scott TE, Ortega AN, Menzoian JO. Functional outcome in limb salvage vascular surgery. Am J Surg 1994;168:188-191

12. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995; 41:1403-1409

13. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-227

14. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: A manual. Groningen: the Northern Centre for Health Care Research, Groningen; 1993

15. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538

16. WHOQOL group. The WHOQOL assessment. (WHOQOL: Development and generic psychometric properties). Soc Sci Med 1998;46:1569-1585

17. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University;1995

18. WHOQOL group. Field trial WHOQOL-100 February 1995. Facet definitions and questions. Geneva: WHO (MNH/PSF/95.1.B);1995

19. Likert R. A technique for the measurement of attitudes, Arch Psychol 1932;140: 55

20. Ware JE, Sherbourne CD. The SF-36 Short Form health status survey 1, conceptual framework and item selection. Med Care 1992;30:473-483

21. Beattie DK, Golledge J, Greenhalgh RM, Davies AH. Quality of life assessment in vascular disease: Towards a consensus. Eur J Vasc Endovasc Surg 1997;13:9-13

22. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardisation. Eur J Vasc Endovasc Surg 1997;13:597-604

23. TASC Working Group. Management of peripheral arterial disease. Trans-atlantic inter-society consensus. J Vasc Surg 2000;31:S 41

24. Bowling A. Measuring disease: A review of disease-specific quality of life measurement scales. Buckingham: Open University Press;1985

25. Hays WL. Statistics. Fourth edition. New York: Rinehart and Winston, Inc. 1988

26. Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297-334

27. De Vries J, Van Heck GL. The World Health Organization Quality of Life assessment instrument (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

28. Slevin M, Plant H, Lynch D, Drinkwater J, Gregory WM. Who should measure quality of life, the doctor or the patient? Br J Cancer 1988;57:109-112

CHAPTER 4

ASSESSMENT OF DISEASE IMPACT IN PATIENTS WITH INTERMITTENT CLAUDICATION

DISCREPANCY BETWEEN HEALTH STATUS AND QUALITY OF LIFE

J.C. Breek*
J. de Vries**
G.L. van Heck**
D.P. van Berge Henegouwen
J.F. Hamming

Dept. of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands
Dept. of Surgery, Martini Hospital, Groningen, The Netherlands*
Dept. of Psychology and Health, Tilburg University, Tilburg, The Netherlands**

Submitted

ABSTRACT

Objective: Quality of life (QOL) is a major outcome in patients with intermittent claudication (IC). Reports on QOL are difficult to interpret and to compare, because the term is often used in studies on health status. This study aims to describe similarities and differences between health status and QOL, as defined by the World Health Organisation (WHO), in patients with IC.

Design: A prospective study in the vascular outpatient clinic of a teaching hospital.

Material and methods: Health status and QOL were assessed in 200 consecutive patients with IC, using the RAND-36 and the WHO QOL assessment instrument. Results were compared with those of sex- and age matched healthy controls. Data were analysed with Mann-Whitney-U tests. A probability value of less than 0.01 was considered to be statistically significant. Pearson correlations were calculated between health status and QOL results. The upper and lower 10% of QOL scores were compared with the quartiles of the health status scores.

Results: Patients' health status was significantly impaired in all domains. QOL was significantly worse with respect to aspects of Physical health, Level of independence, and Overall QOL and general health. Subjective evaluation of functioning disclosed patient-reported problems that had not been identified in health status. Conversely, patients did not regard all objective functional impairments as a problem. Pearson correlations ranged between 0.20 and 0.74. There were patients with excellent and very poor QOL scores in nearly all the response quartiles of the corresponding health status domains.

Conclusions: Health status reflects health-related functional restrictions as a result of disease. QOL also incorporates the subjective appraisal of these restrictions, non-health related aspects, and positive evaluations. Assessment of both objective functioning and subjective appraisal of functioning could direct treatment in a way that meets patients' needs.

INTRODUCTION

Increasingly, health care providers recognise the importance of the patient's perception of disease and the need for a patient-oriented evaluation of treatment modalities, especially in the chronically ill[1]. The patient's perception is generally referred to as quality of life (QOL). However, there is confusion about the terminology concerning QOL. The term is used in a comprehensive way for quantitative objective functional assessment of QOL dimensions, like functional status and health status, and for concepts that also incorporate qualitative subjective personal appraisal of those dimensions[2-5]. The lack of consensus about the definition of QOL and the instruments that claim to measure them has resulted in a plethora of measures purporting to address QOL[2]. The appropriateness and validity of these measures are not always well established. Consequently, the use of these measures for the assessment of unclear concepts that ultimately might affect decisions made about ill people has been questioned[6]. Much of the semantic confusion in reports on QOL is caused by the erroneous use of only health status measures in studies that claim to assess QOL[2,7,8]. After all, for the assessment of the personal perception and evaluation of functioning, which are essential for QOL as defined by the World Health Organisation (WHO)[9], measures should allow for at least some form of subjective appraisal.

The aim of this study is to describe similarities and differences between health status and QOL, and to illustrate the additional value of subjective appraisal to objective assessment in patients with intermittent claudication (IC).

IC is a non-lethal mild expression of chronic progressive atherosclerosis. Despite its benign course for the legs, IC has a major impact on daily life[10] and survival is severely threatened by concomitant cardiac and cerebrovascular disease[11]. Because treatment options are limited to relieve complaints and to slow down disease progression, QOL assessment is of particular interest for patients with IC. Traditionally, disease impact and treatment results for IC are expressed in terms of walking distance, ankle brachial pressure indices (ABPI), and patency of revascularisation procedures[12]. With the purpose to meet the patients' perception of disease impact and treatment effects, the incorporation of health status (or health-related QOL) measurements is recommended to supplement the clinical evaluation of patients with IC[13].

MATERIAL AND METHODS

Patients

Between January 1999 and June 2000 health status and QOL were assessed in all patients presenting with IC at the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands. The diagnosis was suspected on history and physical examination in 215 patients and could be confirmed by treadmill performance (median pain free and maximum walking distance 70 m. and 240 m.) and ABPI (mean 0.62, range 0.33-0.95) in 207 patients. Seven patients refused or were not capable to participate. Two hundred patients were included in the study, 135 men and 65 women with a mean age of 63 years (range 42-83). Risk factors and comorbidity were recorded according to the recommended standards for reports dealing with lower extremity ischemia[12] (Table 1). All patients were matched for age and sex with healthy controls.

Table 1
Distribution of risk factors and comorbidity, specified into "none", "mild", "moderate" and "severe", according to the SVS/ISCVS[12] in 200 patients with intermittent claudication studied for health status and quality of life

	none	mild	moderate	severe
Diabetes Mellitus	168 (84%)	11 (6%)	15 (8%)	6 (3%)
Tobacco use	25 (13%)	43 (22%)	73 (37%)	59 (30%)
Hypertension	106 (53%)	50 (25%)	34 (17%)	10 (5%)
Hyperlipidaemia	94 (47%)	38 (19%)	27 (14%)	41 (20%)
Cardiac status	136 (68%)	37 (19%)	25 (13%)	2 (1%)
Carotid status	172 (86%)	7 (4%)	15 (8%)	6 (3%)
Renal status	192 (96%)	3 (2%)	3 (2%)	2 (1%)
Pulmonary status	179 (90%)	12 (6%)	8 (4%)	1 (1%)

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity: see Appendix III

Definitions

The WHO has defined health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity[14]. Accordingly, health status reflects the influence of disease on physical, emotional, and social functioning. It measures objective functional limitations as a result of disease[15]. For instance, the walking problem in claudicants not only affects mobility, but also may interfere with social activities and patients' mood. In contrast with health status, subjective appraisal of functioning is also incorporated in the measurement of QOL which has been defined by the WHO as "an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations, standards, and concerns. It is a broad ranging concept incorporating in a complex way the individual's physical health, psychological state, level of independence, social relationships, personal beliefs, and

relationships to salient features in the environment"[9]. For example, the level to which a person's QOL is affected by the ability to participate in certain activities also depends on a person's individual preferences.

Instruments

The RAND-36 item health survey (RAND-36)[16,17], which is practically identical to the Medical Outcome Study/Short Form-36 (SF-36)[18], was chosen as health status measure because of its proven applicability in peripheral arterial occlusive disease (PAOD) and to comply with the recommended standardisation of reporting health status/health-related QOL in vascular disease[13,19,20]. The RAND-36 is a 36-item generic multidimensional health status measure. It assesses health in eight dimensions: Physical functioning, Social functioning, Limitations in usual role activities due to physical problems (Role physical), Limitations in usual role activities due to emotional problems (Role emotional), Mental health, Vitality, Bodily pain, and General health perception. In addition, Health changes over the last year may be assessed. Beside scores for each subscale on a scale from 0 to 100, the testing yields a composite health status score. A high score indicates a good health status. The RAND-36 is short and sensitive to intervening illness, for instance, among the relatively healthy elderly. It has a good reliability and validity[21].

QOL was assessed using the WHO Quality of Life assessment instrument-100 (WHOQOL-100)[22,23]. The instrument was chosen, because it corresponds best with the subjective character of the WHO definition of QOL. The WHOQOL-100 is an easy to score generic multidimensional self-report measure with good psychometric properties[24]. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world[9]. It consists of 100 questions assessing 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, Spirituality), and a generic evaluative facet (Overall QOL and general health). Each facet is represented by four questions, reflecting functional limitations and the respondent's personal evaluation of these limitations (How satisfied ..?, How much are you bothered ..?). The response scales are 5-point scales. Scores on each facet and domain can range from 4 to 20. A high score indicates a good QOL, except for the facets Pain en discomfort, Negative feelings, and Dependence on medication and treatments, which have an inverse score. Reliability, validity[3], as well as sensitivity[25] are high, also in healthy elderly[26]. In a preceding study[27](see chapter 3), the instrument has been reduced to those 17 facets (68 questions), that are most relevant for patients with PAOD. Because the original instrument was reduced by eliminating only entire facets, which itself are independent components, the validity and reliability of the WHOQOL-100 were preserved. The scores of the matched controls were collected from the RAND-36 database of the Northern Centre for Health Care Research, Groningen, The Netherlands and from the WHOQOL database of the department of Psychology and Health of Tilburg University, Tilburg, The Netherlands.

The RAND-36 and WHOQOL questionnaires were completed by the patients themselves or, if necessary, with the help of a research assistant. Since the questionnaires together contain 104 questions, it was suspected that the last questions might be given less attention, biasing the study results. To avoid this, the sequence of completion was reversed halfway the inclusion period.

Statistics

Data are expressed in terms of means and standard deviations. Mann-Whitney U-tests were used to detect statistically significant differences ($P < 0.01$) between patients and healthy persons. Pearson correlations were calculated between the RAND-36 domains and the WHOQOL domains/facets. To illustrate the most apparent similarities and differences between health status and QOL, approximately 10% of the patients with the lowest and 10% with the highest scores on a WHOQOL facet or domain were selected. Their scores on corresponding RAND-36 domains were divided into quartiles and visualised in stapled histobars.

RESULTS

Compared with healthy controls, patients scored significantly worse on all RAND-36 domains (Table 2).

Table 2
Scores on the RAND-36 in 200 patients with intermittent claudication and 200 sex and age matched healthy persons

	Healthy persons		Patients		Significance
	m	sd	m	sd	
Physical functioning	70,1	27,3	50,5	19,6	P < .01
Social functioning	85,3	21,8	74,2	24,4	P < .01
Role physical	73,0	39,9	46,3	42,1	P < .01
Role emotional	86,7	28,6	70,4	66,1	P < .01
Mental health	76,8	17,4	70,4	20,4	P < .01
Vitality	65,5	21,6	56,6	20,8	P < .01
Bodily pain	76,2	25,6	58,2	21,6	P < .01
General health perception.	63,7	23,7	56,3	20,3	P < .01

m = mean, sd = standard deviation

Concerning the WHOQOL results, patients evaluated their functioning significantly worse than healthy persons with regard to Physical health and Level of independence. In addition, patients experienced more negative feelings. The social domain was unaffected, but some impairments were recorded in the environmental domain. Finally, Overall QOL and general health were significantly worse in claudicants compared with healthy persons (Table 3).

Table 3
Scores on the reduced WHOQOL-100 in 200 patients with intermittent claudication and 200 sex and age matched healthy persons

	Healthy persons		Patients		Significance
	m	sd	m	sd	
-Overall QOL and general health	16.1	2.5	14.5	2.8	P < .01
Physical health	15.3	2.4	13.4	2.4	P < .01
- Pain and discomfort	9.4	2.8	12.1	2.6	P < .01
- Energy and fatigue	15.2	3.1	12.6	3.0	P < .01
- Sleep and rest	16.2	3.6	15.6	4.0	ns
Psychological health	-		-		
- Positive feelings	14.4	2.0	14.2	2.4	ns
- Thinking, learning, memory, concentration	-		-		
- Self-esteem	14.7	2.2	14.5	2.7	ns
- Body image and appearance	-		-		
- Negative feelings	8.9	2.8	10.1	3.1	P < .01
Level of independence	16.8	2.4	13.1	2.6	P < .01
- Mobility	17.0	3.0	11.7	2.7	P < .01
- Activities of daily living	16.6	2.7	14.0	3.0	P < .01
- Dependence on medication and treatments	7.0	3.1	10.8	3.5	P < .01
- Working capacity	16.7	2.8	13.4	3.7	P < .01
Social relationships	15.3	2.6	15.2	2.7	ns
- Personal relationships	16.0	2.5	16.5	2.7	ns
- Social support	-		-		
- Sexual activity	14.2	4.0	13.8	3.5	ns
Environment	-		-		
- Physical safety and security	-		-		
- Home environment	15.9	2.5	16.1	2.9	ns
- Financial resources	-		-		
- Health and social care	-		-		
- Opportunities for acquiring new information and skills	16.0	2.4	14.7	2.7	P < .01
- Recreation/leisure	15.9	2.7	14.9	3.1	P < .01
- Physical environment	-		-		
- Transport	17.5	3.0	16.5	3.7	ns
Spirituality, religion, personal beliefs	-		-		

m = mean, sd = standard deviation, ns = not significant. The scores on the facets Pain and discomfort, Negative feelings, and Dependence on medication and treatments are inverse. High scores reflect low QOL.

The correlations between the RAND-36 domains and the WHOQOL facets/domains ranged between 0.20 and 0.74. The strongest correlations were found between RAND-36 Mental health and WHOQOL facet Negative feelings, RAND-36 Vitality and WHOQOL facet Energy and fatigue, RAND-36 General health perception and WHOQOL facet Energy and fatigue, RAND-36 Role physical and WHOQOL domain Level of independence, particularly its facet Working capacity, and between RAND-36 Bodily pain and WHQOL facet Pain and discomfort (Table 4).

Table 4
Pearson correlations between the scores on the WHOQOL facets and domains and the RAND-36 domains in 200 patients with intermittent claudication

	PhysF	SocF	RoPh	RoEm	MentH	Vital	Pain	GH
- Overall QOL and general health	.39	.53	.32	.35	.52	.57	.21	.57
Physical health	.47	.50	.46	.39	.56	.57	.48	.53
- Pain and discomfort	-.45	-.35	-.40	-.24	-.42	-.40	-.60	-.30
- Energy and fatigue	.44	.44	.41	.42	.43	.67	.31	.64
- Sleep and rest	.20	.31	.25	.23	.38	.23	.22	.25
Psychological health								
- Positive feelings	.20	.45	ns	.33	.56	.52	ns	.51
- Thinking, learning, memory								
- Self-esteem	ns	.40	.22	.26	.51	.44	ns	.40
- Body image and appearance								
- Negative feelings	-.20	-.43	-.20	-.38	-.74	-.49	ns	-.36
Level of independence	.59	.51	.60	.37	.39	.52	.50	.57
- Mobility	.50	.40	.42	.25	.25	.35	.49	.34
- Activities of daily living	.54	.59	.54	.40	.45	.57	.46	.57
- Dependence med/treatment	-.34	-.22	-.34	ns	-.26	-.25	-.23	-.42
- Working capacity	.49	.41	.60	.41	.28	.47	.42	.47
Social relationships	.28	.44	ns	.26	.49	.45	ns	.37
- Personal relationships	.24	.44	ns	.21	.52	.44	ns	.33
- Social support								
- Sexual activity	ns	.34	ns	.27	.32	.37	ns	.29
Environment								
- Physical safety and security								
- Home environment	.27	.30	.24	.25	.37	.30	ns	.33
- Financial resources								
- Health and social care								
- Information/skills	ns	.28	ns	ns	.28	.29	ns	.28
- Recreation and leisure	.30	.54	.25	.34	.44	.46	.22	.38
- Physical environment								
- Transport	.24	.36	.20	ns	.26	.24	ns	.22
Spirituality, religion, personal beliefs								

Correlations are significant at $P < 0.01$, ns = not significant

Comparison of the health status response quartiles with the best and worst 10% of the corresponding QOL scores showed that there were patients with excellent and very poor scores on various facets and domains of QOL in nearly all health status response quartiles (Figs.1-8, see pages 86-92). Most similarities were found for the physical domains (Figs.1 and 2), while there were discrepancies regarding Social functioning and Bodily pain (figs.3 and 4). The comparison of scores confirmed that RAND-36 Mental health (Fig.5) correlated stronger with the WHOQOL facet Negative feelings, than with the other facets of the WHOQOL domain Psychological health (Figs.6 and 7). Surprisingly, both the upper and lower response quartiles of RAND-36 General health perception contained patients with

excellent and very low scores on the WHOQOL facet Overall QOL and general health (Fig.8).

DISCUSSION

In chronic conditions, relief of symptoms and amelioration of well-being are the main goals of treatment. Therefore, treatment modalities and their outcomes should not be evaluated in terms of technical possibilities and clinical success, but rather in view of the patient's perception of health and QOL. In patients with IC, many aspects of health status and QOL are affected, which may give the impression that the concepts measure the same problem with apparently similar results. Indeed, both health status and QOL assessments disclosed impairments in physical and psychological functioning, and in daily activities. The RAND-36 domains Physical functioning and Role physical showed acceptable correlations with the WHOQOL domain Level of independence. However, the correlations are far from 1.0, which illustrates that common variance is not very high. The agreement between the RAND-36 response quartiles and the upper and lower 10% of the WHOQOL scores confirmed that with regard to the physical domains both assessments comparably discriminate between high and low performance (health status) and high and low satisfaction with performance (QOL) (Figs.1 and 2). However, health status and QOL differed with respect to social functioning. Whereas patients reported significant limitations in RAND-36 Social functioning, the same patients indicated not to feel socially impaired in the corresponding WHOQOL domain. This paradoxical finding may be explained by looking at the content and the accent of the questions assessing health status and QOL. The social domain of the RAND-36 asks how often and to what extent physical health and emotional problems have interfered with (unspecified) social activities. Consequently, the frequency and the intensity of the events that have interfered with social activities will determine the score for Social functioning. Patients with few social contacts score low and thus are considered to have a bad social life or to function on a low social level. The social domain of the WHOQOL incorporates the facet Personal relationships with questions about feeling lonely, about one's satisfaction with relationships in general and with family in particular, and about satisfaction with the ability to support and care for others (Fig.3). Since satisfaction with social contacts is not related to the size of someone's social network[28], few social contacts not necessarily represent social deprivation, but may reflect a patient's preference. Furthermore, the feeling to be appreciated by others for providing care and support may contribute to social well-being as well. Practically, this means that attempts to improve social functioning in patients with IC based solely on health status results may not contribute to a better QOL per se, because patients do not feel socially impaired.

The pain scores for both instruments show a similar pattern. The 2nd and 3rd response quartiles of the RAND-36 domain Bodily pain contain patients with excellent scores on the

corresponding WHOQOL facet Pain and discomfort, indicating to experience no problems in daily life as a result of pain (Fig.4). This finding illustrates the difference between only recording the frequency and intensity of pain, as reflected in health status, and also asking the patient whether his/her life is actually affected by having pain (QOL). In other words, health status may indicate whether there are limitations or not, and QOL also reflects to which extent patients experience these limitations as a problem in daily life. Individual expectations regarding health, the ability to cope with limitations, and the threshold for the tolerance of discomfort modulate objective health status facts into subjective values, which represents one's QOL[29]. Consequently, two persons with identical restrictions in functioning (health status) may evaluate these restrictions (QOL) differently. In other words, a low health status score can coincide with a high score on the corresponding domain of a QOL measure within the same person.

The possibility to appreciate subjective feelings of patients, in addition to objective recording of their frequency and intensity, permits to uncover hidden problems. For example, the RAND-36 scores indicate restrictions in patients' Mental health. The questions concerning Mental health ask the respondent to rate objectively the frequency of feeling nervous, down, calm and quiet, depressed, and happy. However, the feelings that are actually affected cannot be recognised from the aggregated Mental health score. The corresponding facets of the WHOQOL domain Psychological health allow specifying the subjective content of those feelings. The responses showed that patients with IC experience specifically more negative feelings than healthy persons. A stronger correlation between RAND-36 Mental health and the WHOQOL facet Negative feelings, compared to correlations with other facets of the corresponding WHOQOL domain, confirmed this finding. Moreover, all patients in the lowest and the highest quartiles of RAND-36 Mental health belonged to the 10% of patients with the most and the least Negative feelings, respectively (Fig.5). These findings confirm that an excess of negative feelings in claudicants is responsible for the low RAND-36 Mental health score. As a consequence, therapy directed at reducing negative feelings would rather meet these patient's needs than efforts to increase self-esteem.

QOL measurement revealed a significant dependency on medication and treatments in claudicants. The relationship of this finding with the high incidence of risk factors and comorbidity in patients with IC has recently been made plausible[27,30] and deserves attention in treatment strategy. The burden of concomitant disease and the notion to depend on medical services seem to moderate the relevance of walking for the claudicants' QOL and stresses the need for risk factor management and treatment of comorbidity.

An important characteristic of health status measures is the tendency to assess infirmity or disability, rather than health[31]. Questions focus predominantly on the negative consequences of disease and disregard the remaining positive aspects of life. The fact that claudicants did not report less positive feelings or a negative self-esteem in the WHOQOL compared to healthy controls, and the finding that all response quartiles of the RAND-36 domain Mental

health contain patients in the upper 10% of the scores for the facets Positive feelings and Self-esteem illustrate that there are remaining positive evaluations of QOL, despite a broadly deteriorated health status (Figs.6 and 7). Another drawback of health status measures is the disregard of the mutual influence of health and non-health-related aspects of life, like environment[2,6,7]. Claudicants indicated to feel impaired in common, but apparently important aspects of everyday life like acquiring information/skills or the participation in recreation and leisure activities. Assessment of disease impact with health status measures only would miss these problems and prevent subsequent attention.

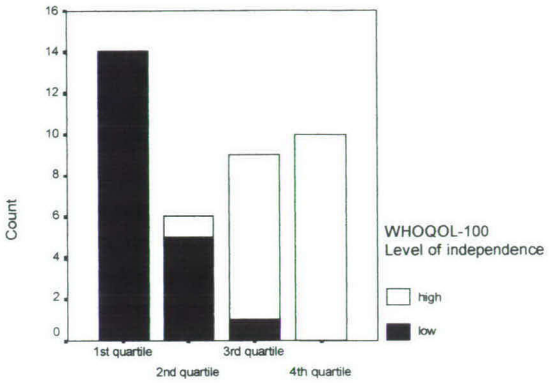
It has been advocated to supplement health status measures with "global QOL" to reflect patients' individual values and preferences[2]. However, for the interpretation of impaired "global QOL" it should be clear what the term represents. Our data show that the WHOQOL facet "Overall QOL and general health" and the closest corresponding RAND-36 domain, General health perception, correlated better with the RAND-36 domain Vitality and its corresponding WHOQOL facet Energy and fatigue, respectively, than with each other. In addition, all response quartiles of the RAND-36 General health perception contained patients with excellent WHOQOL Overall QOL and general health scores (Fig.8). The bare fact that unspecified terms like "General" or "Global" QOL are affected by a certain disease, is too vague to be interpreted and does not add to the understanding of disease impact. Since patients with similar "global QOL" scores may experience different underlying problems, this score will not provide relevant information for disease management. Knowledge of the causal relationships with other aspects of life that actually determine general QOL and health perception may help to interpret these findings and contribute to meaningful treatment.

If health status and QOL measures are used in clinical practice, a problem arises in case the results do not match. Should treatment be based on the functional limitations as indicated by the patient, or be guided by the importance that subjectively has been attributed to these limitations? The answer seems to depend on the kind of disease and the type of study. If functional impairments are mainly responsible for disease impact, which consequently will be reduced by functional improvement, health status may adequately reflect disease impact and serve as a marker of QOL in patient groups[4]. However, in chronic progressive conditions without options for cure, when functional improvement may not reduce disease impact substantially, individual evaluation of all elements that constitute the chronic condition is required to assess a person's QOL. Therefore, to ensure that treatment plans and evaluations focus on the patient rather than on the disease, subjective appraisal should be incorporated in QOL measures[5,32].

In conclusion, our data confirm that health status and QOL are significantly impaired in patients with IC. The subjective character of QOL measurement allowed to identify the problems that are responsible for impaired health status in patients with IC and thus may be given attention. In addition, QOL measurement revealed that an objectively impaired social health status was not necessarily considered as a problem by patients with IC. The

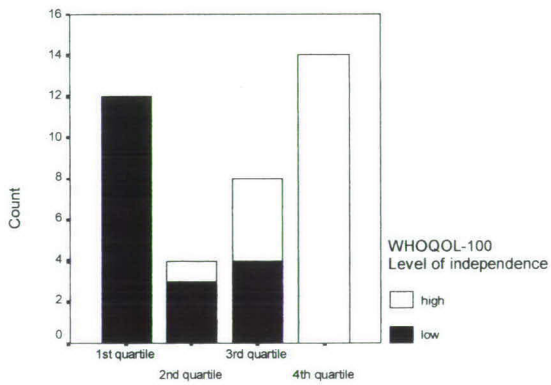
incorporation of positive evaluations and non-health-related aspects of life in the QOL questionnaire disclosed aspects of life that would have been missed with health status measures. Health status measures uncover health-related restrictions that are associated with a certain disease. However, objective health status impairments not necessarily translate into lower levels of QOL. In the present study, the subjective character of QOL measurement allowed to identify the problems that are responsible for the impaired health status in patients with IC and might be given attention. Unexpected positive evaluations, feelings of dependency, and problems with non-health-related aspects of life illustrate that the subjective evaluation of QOL dimensions offers an additional value to the mere recording of functional impairments. QOL assessment without taking account of the claudicants' subjective opinion may be misleading and carries the risk to direct treatment efforts at the wrong targets.

Figure 1



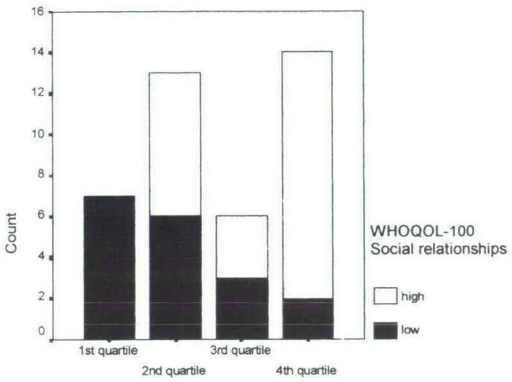
RAND-36 Physical functioning

Figure 2



RAND-36 Role physical

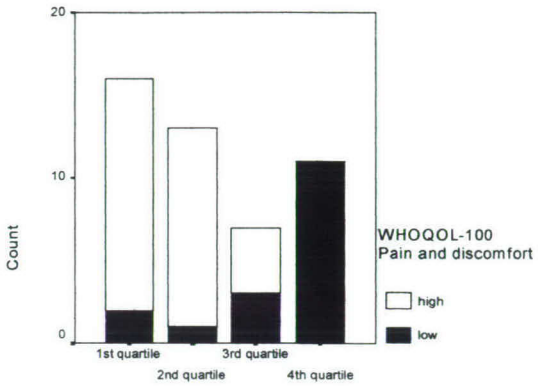
Figure 3



RAND-36 Domain Social functioning:
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?
Not at all – Slightly – Moderately – Quite a bit – Extremely

WHOQOL-100 facet Personal relationships:
How alone do you feel in your life?
Not at all - Slightly – Moderately – Very much - Extremely
Do you feel happy about your relationship with your family members?
Very unhappy – Unhappy – Neither happy nor unhappy – Happy – Very happy
How satisfied are you with your personal relationships?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied
How satisfied are you with your ability to provide for or support others?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied

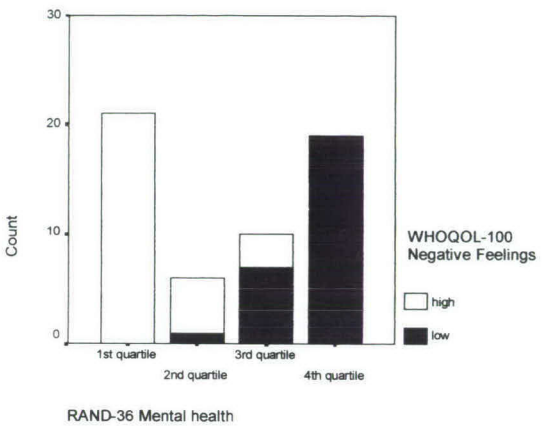
Figure 4



RAND-36 Domain Bodily pain:
How much bodily pain have you had during the past 4 weeks?
None – Very mild – Mild – Moderate – Severe – Very severe

WHOQOL-100 facet Pain and discomfort:
How often do you suffer (physical) pain?
Never – Seldom – Quite often – Very often - Always
Do you worry about your pain or discomfort?
Not al all – A little – A moderate amount – Very much – An extreme amount
How difficult is it for you to handle any pain or discomfort?
Not at all – Slightly – Moderately – Very - Extremely
To what extent do you feel that (physical) pain prevents you from doing what you need to do?
Not al all – A little – A moderate amount – Very much – An extreme amount

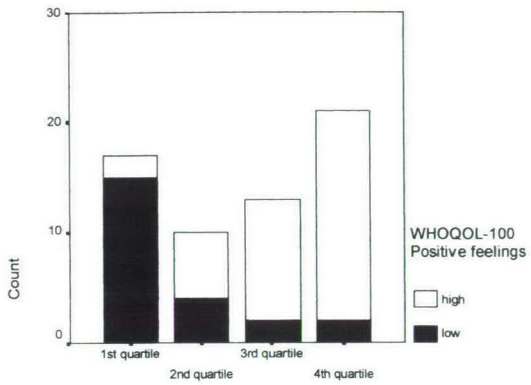
Figure 5



RAND-36 Domain Mental health:
Have you been a very nervous person?
Have you felt so down in the dumps that nothing could cheer you up?
Have you felt calm and peaceful?
Have you felt downhearted and blue?
Have you been a happy person?
All of the time – Most of the time – A good bit of the time – Some of the time – A little of the time – None of the time

WHOQOL-100 facet Negative feelings
How often do you have negative feelings, such as blue mood, despair, anxiety, depression?
Never – Seldom – Quite often – Very often - Always
How worried do you feel?
Not at all – Slightly – Moderately – Very – Extremely
How much do any feelings of sadness or depression interfere with your everyday functioning?
Not al all – A little – A moderate amount – Very much – An extreme amount
How much do any feelings of depression bother you?
Not al all – A little – A moderate amount – Very much – An extreme amount

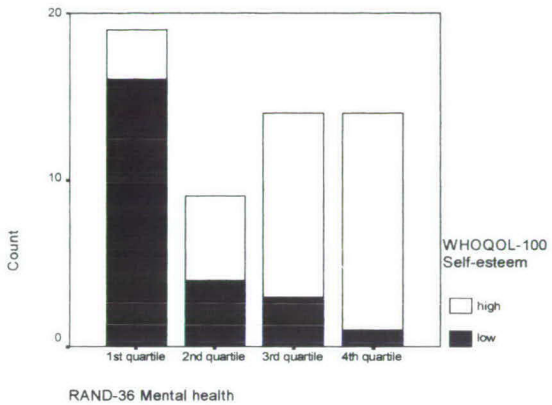
Figure 6



RAND-36 Domain Mental health:
Have you been a very nervous person?
Have you felt so down in the dumps that nothing could cheer you up?
Have you felt calm and peaceful?
Have you felt downhearted and blue?
Have you been a happy person?
All of the tine – Most of the time – A good bit of the time – Some of the time – A little of the time – None of the time

WHOQL-100 facet Positive feelings :
How much do you enjoy life?
Not al all – A little – A moderate amount – Very much – An extreme amount
Do you generally feel content?
Never – Seldom – Quite often – Very often - Always
How positive do you feel about the future?
Not at all – Slightly – Moderately – Very – Extremely
How much do you experience positive feelings in your life?
Not al all – A little – A moderate amount – Very much – An extreme amount

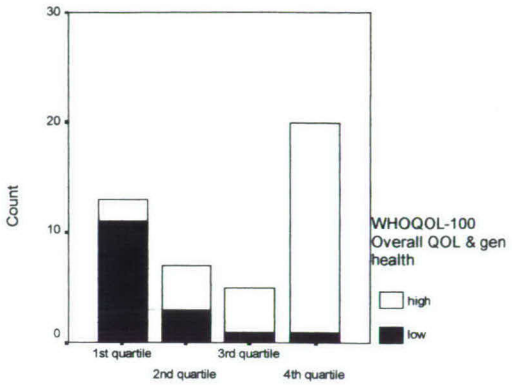
Figure 7



RAND-36 Domain Mental health:
Have you been a very nervous person?
Have you felt so down in the dumps that nothing could cheer you up?
Have you felt calm and peaceful?
Have you felt downhearted and blue?
Have you been a happy person?
All of the tine – Most of the time – A good bit of the time – Some of the time – A little of the time – None of the time

WHOQOL-100 facet Self-esteem:
How much do you value yourself?
Not al all – A little – A moderate amount – Very much – An extreme amount
How much confidence do you have in yourself?
Not al all – A little – A moderate amount – Very much – An extreme amount
How satisfied are you with yourself?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied
How satisfied are you with your abilities?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied

Figure 8



RAND-36 Domain General health perception:
In general, what would you say your health is?
Excellent – Very good – Good – Fair - Poor
How true or false is each of the following statements for you?
I seem to get sick a little easier than other people.
I am as healthy as anybody I know.
I expect my health to get worse.
My health is excellent.
Definitely true – Mostly true – Don't know – Mostly false – Definitely false

WHOQOL-100 facet Overall quality of life and general health:
How would you rate your quality of life?
Very poor – Poor – Neither poor nor good – Good – Very good
How satisfied are you with the quality of your life?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied
In general, how satisfied are you with your life?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied
How satisfied are you with your health?
Very dissatisfied – Dissatisfied – Neither satisfied nor dissatisfied – Satisfied – Very satisfied

REFERENCES:

1. O'Boyle, CA. Assessment of quality of life in surgery. Br J Surg 1992;79:395-398

2. Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of-life measurements. JAMA 1994;272:619-626

3. De Vries J, Van Heck GL. The World Health Organisation Quality of Life assessment (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

4. Covinsky KE, Wu AW, Landefeld CS. et al. Health status versus quality of life in older patients: Does the distinction matter? Am J Med 1999;106:435-440

5. Schalock RL, Bonham GS, Marchand CB. Consumer based quality of life assessment: A path model of perceived satisfaction. In: Evaluation and Program Planning, 23, 77-87, 2000

6. Hunt SM. The problem with quality of life. Qual Life Res 1997;6:205-212

7. Leplege A, Hunt S. The problem of quality of life in medicine. JAMA 1997;278:47-50

8. Bradley C. Importance of differentiating health status from quality of life. Lancet 2001;357:7-8

9. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

10. Breek JC, Hamming JF, De Vries J, Aquarius AEAM, Van Berge Henegouwen DP. Quality of life in patients with intermittent claudication using the World Health Organisation (WHO) Questionnaire. Eur J Vasc Endovasc Surg 2001;21:118-122

11. Dormandy J, Heeck L, Vig S. Lower extremity atherosclerosis as a reflection of a systemic process: Implications for concomitant coronary and carotid disease. Sem Vasc Surg 1999;12:118-122

12. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538

13. TASC working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

14. World Health Organisation. The constitution of the WHO. WHO chronicle 1947;1:29

15. Bergner DK. Measurement of health status. Med Care 1985;23:696-704

16. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-227

17. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: A manual. Groningen: Northern Centre for Health Care Research; 1993

18. Ware JE, Sherbourne CD. The SF-36 Short Form health status survey 1. Conceptual framework and item selection. Med Care 1992;30:473-483

19. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardization. Eur J Vasc Endovasc Surg 1997;13:597-60

20. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: Revising the paradigm for the 21st century. Ad Hoc Committee to Study Outcomes Assessment, Society for Vascular Surgery/ International Society for Cardiovascular Surgery, North American Chapter. J Vasc Surg 2000;32:1239-50

21. Bowling, A. (1991). Measuring health. A review of quality of life measurement scales. Milton Keynes: Open University Press

22. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-1409

23. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University;1995

24. WHOQOL group. The WHOQOL assessment. (WHOQOL: Development and generic psychometric properties). Soc Sci Med 1998;46:1569-1585

25. O'Carroll RE, Cossar JA, Couston MC, Hayes PC. Sensitivity to change following liver transplantation: A comparison of three instruments that measure quality of life. J Health Psychol 2000;5:69-74

26. De Vries J. Beyond health status: Construction and validation of the Dutch WHO quality of life assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

27. Breek JC, Hamming JF, De Vries J, Van Berge Henegouwen DP, Van Heck GL. The impact of walking impairment, cardiovascular risk factors, and comorbidity on the quality of life in patients with intermittent claudication. J Vasc Surg 2002;36:94-99

28. Sarason BR, Sarason IG, Pierce GR. Traditional views of social support and their impact on assessment. In: Sarason BR, Sarason IG, Pierce GR, eds., Social support: An interactional view. New York: Wiley;1990. p. 9-25

29. Testa MA, Simonson DC. Assessment of quality of life outcomes. Current Concepts 1996;334:835-840

30. Dormandy J, Heeck L, Vig S. Intermittent claudication: A condition with underrated risks. Sem Vasc Surg 1999;12:96-108

31. Swenson JR, Clinch JJ. Assessment of quality of life in patients with cardiac disease: The role of psychosomatic medicine. J Psychosom Res 2000;48:405-415

32. Higginson IJ, Carr AJ. Using quality of life measures in the clinical setting. BMJ 2001;322:1297-1300

CHAPTER 5

QUALITY OF LIFE IN PATIENTS WITH INTERMITTENT CLAUDICATION USING THE WORLD HEALTH ORGANISATION (WHO) QUESTIONNAIRE

J.C. Breek*
J.F. Hamming
J. de Vries**
A.E.A.M. Aquarius**
D.P. van Berge Henegouwen

Dept. of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands
Dept. of Surgery, Martini Hospital, Groningen, The Netherlands*
Dept. of Psychology and Health, Tilburg University, Tilburg, The Netherlands**

An adapted version of this chapter has been published in the European Journal of Vascular and Endovascular Surgery 2001;21:118-122
Reproduced with permission from Elsevier

ABSTRACT

Objective: To assess quality of life (QOL) in patients with intermittent claudication (IC).

Design: A prospective study in the vascular outpatient clinic of a teaching hospital.

Material and methods: One hundred and fifty-one consecutive patients with IC (100 men, 51 women) completed a reduced version of the World Health Organisation Quality of Life assessment instrument-100. Results were compared with those of an age-matched group of 161 healthy persons (70 men and 91 women).

Results: Patients scored significantly worse on the domains Physical health and Level of independence, and on the facets Pain and discomfort, Energy and fatigue, Mobility, Activities of daily living, Dependence on medication and treatments, Working capacity, Negative feelings, Recreation and leisure, and Overall QOL and general health. Increasing disease to incapacitating claudication affected only the facet Mobility and the domain Level of independence.

Conclusion: QOL in patients with IC is reduced in many aspects. Where comorbidity seems to affect QOL strongly, the effect of walking distance on QOL might be small. These findings may justify a reserved attitude towards invasive, even minimally invasive treatment of these patients.

INTRODUCTION

Intermittent claudication (IC) is a symptom of peripheral arterial occlusive disease (PAOD), one of the expressions of atherosclerosis, disabling, non-fatal, and with a high prevalence[1]. The severity of claudication is usually assessed by means of the treadmill-walking distance and the ankle brachial pressure index (ABPI). However, neither of these variables correlates well with patient reported functional impairments[2-4]. An alternative way to assess the impairment is therefore required.

Quality of life (QOL) is increasingly recognised as an important and independent measure of disease impact and a measure of outcome of treatment[5,6], and is recommended as a guideline for treatment policy in vascular disease[7]. In the literature, QOL is often used as a comprehensive concept, i.e., concepts like functional status and health status are labeled as QOL. However, functional status refers to physical functioning, for instance, walking distance in claudicants. Health status assesses the influence of disease on physical, social, and emotional functioning; it measures restrictions in functioning[8,9]. Health status measures like the Medical Outcome Study Short Form-36 (SF-36)[10], the Nottingham Health Profile[11] and the Euroqol[12] are frequently used in studies on health status in vascular disease. QOL, as defined by the World Health Organisation (WHO)[13], is a broader concept comprising *the personal evaluation of functioning* with regard to physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment. QOL assesses functioning in relation to the patients' own criteria.

The aim of this study was to measure QOL, as defined by the WHO, in patients with IC.

MATERIALS AND METHODS

Patients

Between January 1999 and December 1999, QOL was assessed in 151 consecutive patients (100 men, 51 women, mean age 63 years, range 43-83 years) presenting with IC at the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands. The diagnosis was made on history, physical examination, treadmill-walking distance, and ankle blood pressure. The impairment was recorded according to a slightly modified version of the reporting standards as recommended by the Society for Vascular Surgery/ the North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS)[14] as mild, 26 patients; moderate, 72 patients; severe, 53 patients. Risk factors and comorbidity are presented in Table 1.

Table 1
Distribution of risk-factors and comorbidity, specified into "none", "mild", "moderate" and "severe", according to the SVS/ISCVS[14] in 151 patients with intermittent claudication, studied for QOL

	none	mild	moderate	severe
Diabetes mellitus	127 (84%)	9 (6%)	11 (7%)	4 (3%)
Tobacco use	27 (18%)	27 (18%)	52 (34%)	45 (30%)
Hypertension	82 (54%)	41 (27%)	20 (13%)	8 (5%)
Hyperlipidaemia	77 (51%)	28 (19%)	15 (10%)	31 (21%)
Cardiac status	99 (66%)	35 (23%)	16 (11%)	1 (1%)
Carotid disease	124 (82%)	8 (5%)	14 (9%)	5 (3%)
Renal status	146 (97%)	3 (2%)	1 (1%)	1 (1%)
Pulmonary status	135 (89%)	9 (6%)	6 (4%)	1 (1%)

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity: see Appendix III

Measure

QOL was assessed using the WHO Quality of Life Assessment Instrument-100 (WHOQOL-100)[15-17]. This is a generic, multidimensional, self-report QOL measure with good psychometric properties that is easy to score[18]. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world[13]. It consists of 100 items assessing 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, Spirituality) and a generic evaluative facet (Overall QOL and general health). Each facet is represented by four items. The responses are expressed in 5-point scales. Scores on each facet and domain can range from 4 to 20. The reliability and validity of the instrument are high[19], also in healthy elderly[17].

To adapt the instrument for patients with PAOD and to limit patient burden of completing 100 questions, the original WHOQOL-100 was reduced to the facets and domains that were relevant to this patient group. After a pilot study (see chapter 3) in 22 patients, using criteria for the distribution of answers (kurtosis, which describes the peakedness of the distribution, and skewness, which means that the length of one of the tails of the distribution, relative to the central section, is disproportionate to the other), and internal consistency (Cronbach's alpha, a measure for the reliability of the instrument[20]), the instrument could be reduced to 17 facets (68 questions), covering the domains Physical health, Psychological health, Level of independence, Social relationships, and Environment and the generic evaluative facet Overall QOL and general health. Because the original instrument was reduced by eliminating only entire facets, which itself are independent components, the validity and reliability of the WHOQOL-100 were preserved.

The patients completed the questionnaire and a research assistant was available for help, if needed. The QOL scores of the examined patient population was put into perspective by comparing them with an age-matched, community based sample of 161 healthy persons, (70

men, 91 women, mean age 62 years, range 40-91 years) from the validation study of the Dutch version of the WHOQOL-100[19].

Statistics

Data are expressed as means and standard deviations. In order to detect statistically significant differences between patients and healthy persons, data were analysed with Mann-Whitney U-tests. Due to the number of facets in the WHOQOL-100 and thus the number of analyses examined, a probability value of less than 0.01 was considered to be statistically significant. The statistical differences between the three categories of IC were analysed with Kruskal-Wallis tests.

RESULTS

Compared with healthy persons, patients scored worse on the domains Physical health and Level of independence, and the facets Pain and discomfort, Energy and fatigue, Mobility, Activities of daily living, Dependence on medication and treatments, and Working capacity. Moreover, patients experienced more negative feelings (Psychological health), as well as problems with respect to Recreation and leisure (Environment). Finally, patients scored significantly lower on Overall QOL and general health (Table 2).

There were no statistically significant differences in the distribution of risk factors and comorbidity between the three categories of IC. The three categories (mild, moderate, and severe claudication) were comparable with regard to QOL, except for the facet Mobility (Table 3). The difference between severe and mild claudication on the domain Level of independence reached a P-value of 0.025. Since the number of domains is much smaller than the number of facets and thus the number of analyses examined, a probability value of less than 0.05 might be accepted to reach statistical significance for the domain Level of independence.

DISCUSSION

The present study highlights the personal and subjective evaluation of functioning in patients with IC. As we reduced the WHOQOL-100, by means of parameters for distribution of answers and internal consistency, the remaining questions are supposed to reflect those facets of life that are of particular importance to these patients.

Analogous to the health status studies, it appears that PAOD, even in its mildest expression, has a detrimental effect on QOL as experienced by the patient, compared with healthy persons. The main part of the difference is found in the facets and domains evaluating physical functioning, as might be expected in these physically impaired patients.

Table 2
Scores on the reduced WHOQOL-100 in 151 patients with intermittent claudication

	Healthy		Patients		Significance
	m	sd	m	sd	
- Overall QOL and general health	16.4	2.1	14.4	2.9	P < .001
Physical health	15.5	2.1	13.2	2.6	P < .001
- Pain and discomfort	9.2	2.8	12.2	2.8	P < .001
- Energy and fatigue	15.4	3.0	12.3	3.3	P < .001
- Sleep and rest	16.4	3.2	15.5	4.3	ns
Psychological health	-		-		
- Positive feelings	14.4	2.0	14.0	2.5	ns
- Thinking, learning, memory, concentration	-		-		
- Self-esteem	14.6	2.1	14.7	2.7	ns
- Body image and appearance	-		-		
- Negative feelings	9.0	2.7	10.1	3.2	P < .005
Level of independence	17.0	2.3	12.7	2.6	P < .001
- Mobility	17.0	2.8	11.4	2.7	P < .001
- Activities of daily living	16.9	2.5	13.8	3.4	P < .001
- Dependence on medication, treatments	6.5	2.6	11.4	3.6	P < .001
- Working capacity	16.8	2.9	13.2	3.8	P < .001
Social relationships	15.6	2.3	15.3	2.8	ns
- Personal relationships	16.3	2.4	16.5	2.8	ns
- Social support	-		-		
- Sexual activity	14.8	3.7	13.8	3.9	ns
Environment	-		-		
- Physical safety and security	-		-		
- Home environment	15.9	2.4	15.9	3.2	ns
- Financial resources	-		-		
- Health and social care.	-		-		
- Opportunities for acquiring new information and skills	15.5	2.5	14.8	2.8	ns
- Participation in and opportunities for recreation/leisure	15.9	2.6	14.9	3.2	P = .01
- Physical environment	-		-		
- Transport	17.4	3.1	16.3	3.7	ns
Spirituality, religion, personal beliefs	-		-		

m = mean, sd = standard deviation, ns = not significant
The scores on the facets Pain and discomfort, Negative feelings and Dependence on medication and treatments are inverse. High scores reflect low QOL.

Table 3
Scores on the domain Level of independence and the facet Mobility of the WHOQOL-100 according to the grade of intermittent claudication in 151 patients

Domain Level of independence:	m	sd		m	sd	Significance
Mild claudication	13.7	2.4 compared with	Moderate	12.8	2.7	ns
			Severe	12.0	2.4	P = .025
Moderate claudication	12.8	2.7 compared with	Severe	12.0	2.4	ns

Facet Mobility:	m	sd		m	sd	Significance
Mild claudication	12.6	2.7 compared with	Moderate	12.0	2.7	ns
			Severe	10.1	2.0	P <.001
Moderate claudication	12.0	2.7 compared with	Severe	10.1	2.0	P <.001

m = mean, sd = standard deviation, ns = not significant

The significantly greater dependence on medication and treatments in claudicants as expressed in the results is not directly related to an impaired walking distance and suggests an impact of comorbidity on QOL. This is not surprising since patients suffering from PAOD are known to be affected with important comorbidity[21]. There are several reports in the literature on health status in patients with IC. Pell[22], Currie[23] and Chetter[24,25] using the SF-36 and Euroqol, found that patients were impaired in physical, psychological, and social functioning, deteriorating with the severity of claudication. This was especially the case in multi-level disease. The explicit negative feelings as reported by the patients in this study did not emerge from the health status studies, because health status measures do not evaluate subjective feelings of patients. We feel that disregarding subjective feelings of patients is one of the important disadvantages of merely assessing health status in chronically ill patients, especially when treatment is mainly palliative.

Surprisingly, the three categories of claudicants differed only significantly with regard to the facet Mobility. In addition, the patients with the mildest and the patients with the most severe form of claudication differed on the domain Level of independence. With regard to the other domains and facets of QOL the categories were comparable. This means that, with increasing disease to incapacitating claudication, QOL only deteriorates on these two aspects. The severity of claudication does not seem to be related to the level of QOL other than Mobility and Level of independence. Apparently, the presence of IC, irrespective of the severity, is enough to create a significant difference on the various domains and facets of QOL compared with the healthy population.

It is important to realise that the scores on QOL as presented in this study are the result of all influences of PAOD and comorbidity. The relative impact of comorbidity, in addition to the impaired walking distance on QOL, has not yet been elucidated. The observation that increasing claudication only affects Mobility and Level of independence suggests that successful treatment in terms of improving the walking distance may have a limited effect on QOL on the whole. Although not proven yet, it seems that comorbidity may have a dominant effect on the QOL of patients with IC, whereas the impaired walking distance might be no more than the expression of a more complex underlying disease.

Considering the above, the importance of the walking distance as the principal factor in the assessment of patients with IC should be questioned. The importance of comorbidity is generally underestimated in the literature and that is why we feel that invasive therapy, even minimally invasive, is questionable in patients with IC and serious comorbidity. Future studies should determine the influence of all factors affecting QOL in patients with IC, as it seems to depend on more than walking a few hundred metres more or less.

Because functional assessment and subjective evaluation of functioning are considered complementary concepts[26], they should be used together in order to evaluate the impact of PAOD on the life of patients IC. Since this is the first study to evaluate QOL in patients with IC with a true QOL questionnaire, further study is necessary to determine the complementary value of QOL on health status in these patients.

REFERENCES

1. Fowkes FGR, Housley E, Cawood EHH. et al. Edinburgh Artery Study. Prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. Int J Epidemiology 1991;20:384-392

2. Watson CJE, Phillips D, Hands L, Collin J. Claudication distance is poorly estimated and inappropriately measured. Br J Surg 1997;84:1107-1109

3. Perkins JMT, Collin J, Creasy TS, Fletcher EWL, Morris PJ. Exercise training versus angioplasty for stable claudication. Long and medium term results of a prospective randomised trial. Eur J Vasc Surg 1996;11:409-413

4. Chetter IC, Dolan P, Spark JI, Scott DJA, Kester RC. Correlating clinical indicators of lower-limb ischaemia with quality of life. Cardiovascular Surgery 1997;5:361-366

5. Fraser SCA. Quality of life measurement in surgical practice. Br J Surg 1993;80:163-169

6. Velanovic V. Using quality-of-life instruments to assess surgical outcomes. Surgery 1999;126:1-4

7. Chetter IC, Scott DJA, Kester RC. An introduction to quality of life analysis: The new outcome measure in vascular surgery. Eur J Vasc Endovasc Surg 1998;15:4-6

8. Bergner DK. Measurement of health status. Med Care 1985;23:696-704

9. Stoker MJ, Dunbar GC, Beaumont G. The SmithKline Beecham 'quality of life' scale: A validation and reliability study in patients with affective disorder. Quality Life Res 1992;1:385-395

10. Ware JE, Sherbourne CD. The SF-36 Short Form health status survey 1, conceptual framework and item selection. Med Care 1992;30:473-483

11. Hunt SM, McEwen J, McKenna SP. Measuring health status: a new tool for clinicians and epidemiologists. J R Coll Gen Prac 1985;35:185-188

12. The Euroqol group. Euroqol: a new facility for measurement of health related quality of life. Health Policy 1990;16:199-208

13. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

14. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538

15. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-1409

16. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University;1995

17. De Vries J. Beyond health status: Construction and validation of the Dutch WHO Quality of Life assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

18. WHOQOL group. The WHOQOL assessment. (WHOQOL: Development and generic psychometric properties). Soc Sci Med 1998;46:1569-1585

19. De Vries J, Van Heck GL. The World Health Organisation Quality of Life assessment instrument (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

20. Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297-334

21. Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999:12:123-137

22. Pell JP. Impact of Intermittent claudication on quality of life. The Scottish Vascular Audit Group. Eur J Vasc Endovasc Surg 1995;9:469-472

23. Currie IC, Wilson IG, Baird RN, Lamont PM. Treatment of intermittent claudication: The impact on quality of life. Eur J Vasc Endovasc Surg 1995;10:356-361

24. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardization. Eur J Vasc Endovasc Surg 1997;13:597-604

25. Chetter IC, Spark JI, Kent PJ, Berridge DC, Scott DJA, Kester RC. Percutaneous transluminal angioplasty for intermittent claudication: Evidence on which to base the medicine. Eur J Vasc Endovasc Surg 1998;16:477-484

26. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27:S217-S232

CHAPTER 6

THE IMPACT OF WALKING IMPAIRMENT, CARDIOVASCULAR RISK FACTORS, AND COMORBIDITY ON QUALITY OF LIFE IN PATIENTS WITH INTERMITTENT CLAUDICATION

J.C. Breek*
J.F. Hamming
J. de Vries**
D.P. van Berge Henegouwen
G.L. van Heck**

Dept. of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands
Dept. of Surgery, Martini Hospital, Groningen, The Netherlands*
Dept. of Psychology and Health, Tilburg University, Tilburg, The Netherlands**

An adapted version of this chapter has been published in the Journal of Vascular Surgery 2002;36:94-99
Reproduced with permission from Elsevier

ABSTRACT

Objective: To assess the impact of walking impairment, cardiovascular risk factors, and comorbidity on quality of life (QOL) in patients with intermittent claudication (IC).

Design: A prospective study in the vascular outpatient clinic of a teaching hospital.

Material and methods: QOL was assessed in 200 consecutive patients with IC, with a reduced version of the World Health Organisation Quality of Life Assessment Instrument-100. The reduced instrument assesses 17 facets of QOL within five domains (Physical health, Psychological health, Level of independence, Social relationships, Environment). Age, sex, degree of IC, risk factors and comorbidity, as recommended by the Society for Vascular Surgery/ North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS), and the presence of back, hip, or knee symptoms were analysed as possible predictors of QOL. Multiple regression analyses were run with each of the QOL facets and domains as dependent variable. A probability value of less than 0.05 was considered to be statistically significant.

Results: Male sex was found to be a predictor of better scores for the facets Energy and fatigue, and Sleep and rest. Women experienced more negative feelings. The presence of back, hip, or knee symptoms was of significant predictive value for many aspects of QOL. With more concomitant diseases, patients had lower scores on the facets Overall QOL and general health and Energy and fatigue, and showed more dependence on medication and treatments. The severity of IC, as expressed in the SVS/ISCVS classification, was a statistically significant predictor of QOL for the domain Level of independence and its facets Mobility, Activities of daily living, and Working capacity and the facets Pain and discomfort, Sexual activity, and Transport. Hypertension was the second most important single predictor of QOL in patients with IC.

Conclusion: QOL in patients with IC is only partially determined by the degree of IC as expressed in the SVS/ISCVS classification. The significant impact of cardiovascular risk factors and comorbidity and the presence of back, hip, or knee symptoms on QOL should be recognised and taken into account in the treatment policy.

INTRODUCTION

Intermittent claudication (IC) is a frequently occurring expression of peripheral arterial occlusive disease (PAOD), usually with a benign course for the legs[1]. Although the presenting complaint may seem innocent, concomitant coronary and cerebrovascular disease are serious threats to the claudicant's life[2]. Treatment results in patients with IC are traditionally expressed as changes in ankle blood pressures and walking distance[3]. Because atherosclerosis is a chronic progressive and incurable disease, relief of complaints was the main goal of treatment, for a long time. However, during the last years, quality of life (QOL) has become an accepted measure of disease impact and therapeutic outcome in patients with vascular disease[4-7]. Accordingly, the goal of treatment in patients with IC has shifted from mere palliation of symptoms to the preservation or improvement of QOL. The impact of IC on QOL has been highlighted in several studies[8-10]. However, in these studies the role of cardiovascular risk factors and the impact of concomitant disease on the QOL of these patients are generally not included as a variable. Therefore, the aim of this study was to assess the relative impact of age, sex, severity of claudication, cardiovascular risk factors, comorbidity, and the presence of back, hip, or knee symptoms on QOL in patients with IC.

MATERIAL AND METHODS

Patients

Between January 1999 and June 2000 QOL was assessed in patients with IC, who agreed to participate in the study, at the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands. Two hundred patients were included in the study: 135 men and 65 women, with a mean age of 63 years (range: 42 to 83 years). Diagnosis was suspected on history and physical examination in 215 patients and could be confirmed by treadmill performance, and ankle blood pressure in 207 patients. Seven of them refused or were not capable to participate. Apart from patients with dementia and those who were blind or deaf, no patients were excluded from the study. In all patients the degree of IC, risk factors (smoking and hyperlipidaemia) and comorbidity (hypertension, cardiac, carotid, renal and pulmonary status, diabetes mellitus) were recorded according to the Society for Vascular Surgery/ North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS)[3] (Tables 1 and 2). Because of the impact on mobility, the presence of back, hip, or knee symptoms, unrelated to vascular disease, was also recorded.

Table 1
Characteristics of 200 patients with intermittent claudication, studied for quality of life

	mild claudication	moderate claudication	severe claudication
Nr. of patients	37	81	82
Sex	31 M / 6 F	53 M / 28 F	51 M / 31 F
Mean age	60.6 yrs.	63.7 yrs.	62.8 yrs.
ABI	0.70 (0.52-0.95)	0.68 (0.33-0.93)	0.53 (0.24-0.88)

Mild claudication: Completes modified treadmill exercise*; ankle pressure after exercise > 50 mm Hg, but at least 20 mm Hg lower than resting value. Moderate claudication: Between mild and severe. Severe claudication: Cannot complete modified treadmill exercise and ankle pressure after exercise < 50 mm Hg.
* 3,5 km/h on a 5% incline with a maximum of 1000 m. ABI = ankle brachial index

Table 2
Distribution of risk factors and comorbidity, specified into "none", "mild", "moderate" and "severe", according to the SVS/ISCVS in 200 patients with intermittent claudication studied for quality of life

	none	mild	moderate	severe
Diabetes Mellitus	168 (84%)	11 (6%)	15 (8%)	6 (3%)
Tobacco use	25 (13%)	43 (22%)	73 (37%)	59 (30%)
Hypertension	106 (53%)	50 (25%)	34 (17%)	10 (5%)
Hyperlipidaemia	94 (47%)	38 (19%)	27 (14%)	41 (20%)
Cardiac status	136 (68%)	37 (19%)	25 (13%)	2 (1%)
Carotid status	172 (86%)	7 (4%)	15 (8%)	6 (3%)
Renal status	192 (96%)	3 (2%)	3 (2%)	2 (1%)
Pulmonary status	179 (90%)	12 (6%)	8 (4%)	1 (1%)

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity: see Appendix III

Instrument

QOL was assessed with a reduced version of the World Health Organization Quality of Life Assessment Instrument-100 (WHOQOL-100)[11-13]. The WHOQOL-100 is a generic, multidimensional, self-report QOL measure that is easy to score and has good psychometric properties[14]. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world[15]. It consists of 100 questions for the assessment of 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, Spirituality/Religion/Personal beliefs) and a generic evaluative facet, Overall QOL and general health. Each facet is represented by four questions. The response scales are 5-point scales. Scores on each facet and domain can range from 4 to 20. A higher score indicates that respondents evaluate their functioning on the respective domains and facets of QOL as being better, except for the facets Pain and discomfort, Negative feelings

and Dependence on medication and treatments, which have an inverse score. The reliability and validity of the instrument are high[16], also in healthy elderly[13].
After a pilot study in 22 patients with PAOD, using criteria for response distribution (kurtosis, which describes the peakedness of the distribution, and skewness, which means that the length of one of the tails of the distribution, relative to the central section, is disproportionate to the other), and internal consistency (Cronbach's alpha, a measure for the reliability of the instrument), the instrument could be reduced to 17 facets (68 questions), covering the domains Physical health, Psychological health, Level of independence, Social relationships, and Environment and the generic evaluative facet Overall QOL and general health (see chapter 3). Because the original instrument was reduced by eliminating only entire facets, which itself are independent components, the validity and reliability of the WHOQOL-100 were preserved.

Statistics
Age, sex, risk factors, comorbidity, and SVS/ISCVS classification of IC were tested as possible predictors of QOL. Multiple regression analyses (MRAs) were run with each of the QOL facets and domains as dependent variable. Each MRA (stepwise method) consisted of four blocks of variables.
The demographic variables, sex and age, were entered in block 1. The second block consisted of the presence of back, hip, or knee symptoms. Block 3 contained the risk factors smoking and hyperlipidaemia. Two series of MRAs were run, with the fourth block containing the number of concomitant diseases in the first series and nature of the concomitant disease (hypertension, cardiac, carotid, renal and pulmonary status, diabetes mellitus) and the severity of IC in the second series. Before performing MRA's, we examined the distributions of the variables involved. In the case of carotid, renal, and pulmonary status, exploration revealed extreme skewness and kurtosis scores that could not be improved satisfactory by logarithmic transformations. Furthermore, additional data exploration pointed at violations of the linearity assumption. Taken these results of evaluation together, it was decided to dichotomise the measures of these variables to absent or present. The degree of IC and the severity of risk factors and comorbidity are expressed as none, mild, moderate, or sever, which means that the predictive value of these independent variables on QOL correlates with the change and direction (increase or decrease) of the severity. Differences in age, distribution of risk factors, and comorbidity between the three categories of claudication were tested with Kruskal-Wallis tests. A possible difference in sex between the three categories of IC was examined using a Chi-square test. For all calculations, a probability value of less than 0.05 was considered to be statistically significant.

RESULTS

No statistically significant differences were found in age and sex, or in the distribution of risk factors and comorbidity between the three categories of IC. Back, and hip, or knee symptoms were present in 13% and 10% of the patients, respectively.

Male sex was a major predictor for higher scores on the domain Physical health and its components, Energy and fatigue, and Sleep and rest. Female sex associated exclusively with more negative feelings.

From the first series of MRAs (Table 3) patients with more concomitant diseases appeared to have lower scores on Overall QOL and general health, Energy and fatigue, and Dependence on medication/treatments. When patients had back, hip, or knee symptoms, their QOL scores were lower on all facets except for Sleep and rest, Negative feelings, Dependence on medication/treatments, Home environment, and Opportunities for acquiring new information/skills.

The second series of MRAs (Table 4) showed that increasing IC predicted a lower QOL on the domain Level of independence and its facets Activities of daily living and Working capacity. Moreover, the severity of IC was the only variable with a substantial predictive value for the facet Mobility (domain Level of independence). In addition, more severe IC is associated with more Pain and discomfort, lower scores on the facet Sexual activity, and more problems with Transport. Hypertension emerged as an important factor for QOL with a significant predictive value for various aspects such as Overall QOL and general health, Energy and fatigue, the domain Level of independence and its facets Dependence on medication/treatments and Working capacity, as well as for the facets Recreation/leisure and Transport.

Specifically, non-smokers, patients with a mild smoking behaviour, and patients with a compromised carotid or pulmonary status indicated that they felt more dependent on medication and treatments. Patients with pulmonary restrictions had higher scores for the facet Sleep and rest, while patients with hyperlipidaemia scored lower for Self-esteem.

Age and diabetes mellitus had no significant predictive value for any QOL aspects in patients with IC. Finally, no significant predictors of QOL were seen on the domain Social relationships and the facets Personal relationships and Home environment.

Table 3
Results from stepwise multiple regression analysis with age, sex, non-vascular back, hip and knee symptoms, risk factors, and number of concomitant diseases as independent variables (predictors of quality of life) and the WHOQOL facets and domains as dependent variables in 200 patients with intermittent claudication

Dependent variable	Predictor of QOL	Beta	R^2 change	R^2 Total
- Overall QOL and general health (P < .002)	Back pain	-.248	.068	.068
	Comorbidity	-.214	.046	.114
Physical health (P < .001)	Sex	-.348	.096	.096
	Back pain	-.312	.096	.192
- Pain and discomfort (P<.002)	Back pain	-.290	.084	.084
- Energy and fatigue (P < .001)	Sex	-.276	.054	.054
	Back pain	-.202	.044	.098
	Comorbidity	-.221	.049	.147
- Sleep and rest (P < .004)	Sex	-.270	.073	.073
Psychological health	-	-	-	-
- Positive feelings (P < .046)	Back pain	-.191	.036	.036
- Thinking, learning, memory, concentr.	-	-	-	-
- Self-esteem (P < .024)	Back pain	-.217	.047	.047
- Body image and appearance	-	-	-	-
- Negative feelings(P < .003)	Sex	.282	.079	.079
Level of independence (P < .005)	Back pain	-.268	.072	.072
- Mobility (P < .020)	Back pain	.221	.049	.049
- Activities of daily living (P < .048)	Hip/knee symptoms	-.190	.036	.036
- Dependence on medication and treatments (P < .005)	Comorbidity	.324	.168	.168
- Working capacity (P < .001)	Back pain	-.367	.158	.158
	Hip/knee symptoms	-.220	.047	.205
Social relationships (P < .013)	Back pain	-.253	.054	.054
- Personal relationships (P < .041)	Back pain	-.195	.038	.038
- Social support	-	-	-	-
- Sexual activity (P < .036)	Back pain	-.217	.047	.047
Environment	-	-	-	-
- Physical safety and security	-	-	-	-
- Home environment	No significant predictors			
- Financial resources	-	-	-	-
- Health and social care	-	-	-	-
- Opportunities for acquiring new information/skills (P < .040)	Smoking	.196	.038	.038
- Recreation/leisure (P < .001)	Back pain	-.324	.105	.105
- Transport (P < .026)	Hip/knee symptoms	-.213	.045	.045
Spirituality, religion, personal beliefs	-	-	-	-

Legend: see table 4

Table 4
Results from stepwise multiple regression analysis with age, sex, non-vascular back, hip or knee symptoms, cardiovascular risk factors, comorbidity (SVS/ISCVS classification), and degree of intermittent claudiaction (SVS/ISCVS classification) as independent variables (predictors of quality of life) and the WHOQOL facets and domains as dependent variables in 200 patients with intermittent claudication

Dependent variable	Predictor of QOL	Beta	R^2 change	R^2 Total
- Overall QOL and gen. health (P < .001)	Hypertension	-.248	.061	.061
Physical health (P < .001)	Male sex	-.306	.089	.089
	Back pain	-.206	.037	.126
	Renal status	-.174	.030	.156
- Pain and discomfort (P < .001)	Back pain	.312	.087	.087
	IC classification	.151	.023	.110
- Energy and fatigue (P < .007)	Male sex	-.173	.034	.034
	Hypertension	-.155	.024	.058
- Sleep and rest (P < .001)	Male sex	-.308	.091	.091
	Pulmonary status	.156	.024	.115
Psychological health	-	-	-	-
- Positive feelings (P < .007)	Renal status	-.207	.043	.043
- Thinking, learning, memory, concentration	-	-	-	-
- Self-esteem (P < .008)	Hyperlipidaemia	-.205	.042	.042
- Body image and appearance	-	-	-	-
- Negative feelings (P < .001)	Female sex	.297	.088	.088
Level of independence (P < .001)	Hypertension	-.218	.053	.053
	IC classification	-.208	.043	.096
- Mobility (P < .001)	IC classification	-.290	.084	.084
- Act. daily living (P < .008)	IC classification	-.204	.042	.042
- Dependence on medication and treatments (P < .001)	Smoking	-.161	.036	.036
	Hypertension	.254	.073	.109
	Pulmonary status	.170	.032	.141
	Carotid status	.165	.026	.167
- Working capacity (P < .001)	Back pain	-.255	.040	.040
	Hypertension	-.226	.054	.094
	IC classification	-.166	.027	.121
Social relationships	No significant predictors of QOL			
- Personal relationships	No significant predictors of QOL			
- Social support	-	-	-	-
- Sexual activity (P < .006)	Carotid status	-.216	.033	.033
	IC classification	-.195	.037	.070

Table 4 (cont.)

Dependent variable	Predictor of QOL	Beta	R^2 change	R^2 Total
Environment	-	-	-	-
- Physical safety and security	-	-	-	-
- Home environment	No significant predictors of QOL			
- Financial resources	-	-	-	-
- Health and social care	-	-	-	-
- Opportunities for acquiring new information/skills (P < .023)	Cardiac status	-.175	.031	.031
- Recreation/leisure (P < .009)	Hypertension	-.201	.041	.041
- Physical environment	-	-	-	-
- Transport (P < .003)	IC classification	-.192	.041	.041
	Hypertension	-.162	.026	.067
Spirituality, religion, personal beliefs	-	-	-	-

Legend to tables 3 and 4:
Scores on the facets Pain and discomfort, Negative feelings, and Dependence on medication/treatments are inverse. Higher scores indicate lower QOL.
IC classification: mild, moderate, or severe IC according to a modification of the SVS/ISCVS[3].
Beta-value indicates whether relation between a predictor and a facet of QOL is positive or negative. In Table, negative beta-value indicates that low scores on the independent variables (mild claudication, absence of back, hip, or knee symptoms, absence of carotid, renal and pulmonary comorbidity, less severe diabetes mellitus, tobacco use, hypertension, hyperlipidaemia and cardiac comorbidity) predict a higher score on the dependent variables (i.e., the respective domains or facets of QOL). Negative beta-value for sex indicates male sex to be a predictor of QOL, a positive beta-value means that female sex is the predictor of QOL facet or domain.
R^2-change indicates proportion of variance of the dependent variable (i.e., facet or domain of QOL) that is explained by independent variable in that row.
R^2-total reflects total proportion of variance of dependent variable that is explained by independent variables that are included in model up to that point.
Significance of used model is expressed with P-value. P-value < 0.05 was considered statistically significant.

DISCUSSION

QOL scores in patients with IC are the resultant of influences of PAOD and comorbidity. Because the walking impairment is only one of the components of the clinical entity, other aspects should be evaluated as well to understand the impact of IC on patient's QOL. These results show that the predictive value of the walking impairment, as expressed in the modified SVS/ISCVS classification, for the claudicants' QOL is limited to the physical aspects of QOL: Pain and discomfort, Mobility, Activities of daily living, Working capacity, Sexual activity, and Transport. This is in concordance with earlier reports, describing the limited effect of increasing IC on QOL on the whole[10,17]. The importance of risk factors and comorbidity for the development of PAOD and for the prognosis of patients with it has been documented extensively[2,18,19]. For instance, IC appeared to be a substantial predictor of cardiovascular morbidity and mortality, independent of associated coronary ischaemia or other cardiovascular

risk factors in ambulatory elderly[20]. Although patients seek help for a walking problem, the systemic risk of PAOD is the real threat to their lives. Facing this reduces IC to a relatively innocent ailment marking a more serious underlying disease.

These data indicate that, in addition to the walking impairment, concomitant disease plays an important role for most aspects of QOL in patients with IC. This does not detract from the value of improved walking for a better functional status, which will be appreciated by the patient, even in the presence of important comorbidity. However, the gains with respect to QOL may be small, since the predictive value of the walking impairment is limited to physical aspects. Concerning the finding that increasing IC only affects QOL with regard to the facet Mobility[10], patients with IC and important comorbidity may gain some improvement in functional status, but are unlikely to enjoy important QOL benefits from improving walking distance only. Optimising their medical condition may be of greater importance for QOL.

Patients with pulmonary restrictions have better scores for Sleep and rest. Because QOL assesses the personal evaluation of functioning, this subgroup of patients, with predominantly mild to moderate pulmonary impairments (Table 2), apparently appreciate sleep to compensate for the efforts of dyspnoea.

Heavy smokers indicate less dependence on medication and treatments. Although this may seem contradictory, one might speculate that the perception of dependence of a person who is used to dependence on tobacco has been modulated. In other words, dependence as observed, may not be experienced as such.

The importance of back, hip, or knee symptoms for QOL in patients with IC is in concordance with Feinglass et al.[21], who reported on its negative predictive value for physical functioning. Non-vascular back, hip, or knee symptoms are relatively frequent in patients with IC and appeared significant predictors for many aspects of QOL. If present in claudicants, these symptoms should not be ignored, but treated. Relief of these symptoms promises a more profound influence on QOL than attempting to improve the peripheral vascular status.

No significant predictive value was seen for age. Except for the study by Barletta et al.[17], who found a relation between age and health status in patients with IC, this finding is concordant with most other studies. More surprising were the findings that diabetes mellitus neither has a predictive value for QOL, while hypertension appeared to be a major predictor. This may be explained by the fact that many of the usual risk factors and comorbidity that constitute QOL in patients with IC are present in diabetics as well. QOL in patients with IC and diabetes mellitus may be determined largely by the same factors. Moreover, the milder forms of diabetes can be treated by diet and life style modification, with the purpose to keep glucose level within limits. This relatively small interference with daily life and the knowledge that severe complications of diabetes are not evident for 15 to 20 years after its onset may account for diabetes being not a predictor of QOL in patients with IC. While the severity of diabetes according to the SVS/ISCVS reporting standards[3], depends on the age of onset of the disease

and the method of treatment, the severity of hypertension is rated according to the number of drugs needed to control it. The number of anti-hypertension drugs needed every day directly confronts the patient with the severity of this condition, generally known to be associated with important implications for the vascular and cardiac status. The way of rating the severity of diabetes and hypertension may be responsible for the counter-intuitive findings concerning the predictive value of these two variables for QOL in patients with IC.

Although convincing evidence exists that conservative treatment should be the first choice for patients with IC[22,23], the increasing possibilities of minimally invasive, percutaneous procedures have contributed to more active ways of treatment. Studies that focus on patients with IC have shown that percutaneous transluminal angioplasty (PTA) may produce favourable results with respect to patency, ankle-brachial pressure indices, walking distance and even health-related QOL in the short term[24-26]. However, mid-term and long-term results failed to demonstrate benefits from PTA over exercise training and sanitation of risk factors. Deterioration of QOL, 12 months after a successful PTA, has been attributed to the impact of increasing comorbidity[27,28]. The results of the present study show that risk factors and comorbidity also have an important impact on QOL in patients with IC at baseline, before treatment. Thus, successful treatment in terms of improving walking distance only will have a limited effect on the patients' QOL.

The clinical importance of the statistically significant predictors of QOL in this study may be questioned due to the modest strength of the association between dependent and independent variables. In the absence of an alternative method to assess the importance of these variables and facing the fact that patients with IC are known to be suffering from important comorbidity, the results of the present study may help to direct treatment options in a way to satisfy patient's needs.

In the Transatlantic Inter-Society Consensus document (TASC)[6], the statement is found that, although the limitation in walking may be the only symptom of PAOD, the overriding issue in the management of patients with IC is their risk of development of severe and often fatal cardiovascular complications. In addition, this study indicates that the appraisal of risk factors and comorbidity in patients with IC is essential for the interpretation of QOL assessments. It is a challenge for those caring for patients with IC to explain to them the importance of treating comorbidity and risk factors instead of only proposing attractive modalities of palliation for their walking problem.

REFERENCES

1. Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999:12:123-137

2. Dormandy J, Heeck L, Vig S. Lower extremity atherosclerosis as a reflection of a systemic process: Implications for concomitant coronary and carotid disease. Sem Vasc Surg 1999;12:118-122

3. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538.

4. Chetter IC, Scott DJA, Kester RC. An introduction to QOL analysis: The new outcome measure in vascular surgery. Eur J Vasc Endovasc Surg 1998;15:4-6

5. Golledge J, Garrat A, Greenhalgh RM, Davies AH. Patient-assessed health outcome in peripheral arterial disease. Eur J Vasc Endovasc Surg 2000;19:109-110

6. TASC working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

7. Feinglass, J. Morasch M., McCarthy W.J. Measures of success and health-related quality of life in lower-extremity vascular surgery. Ann Rev Med 2000;51:101-113

8. Pell JP. Impact of intermittent claudication on quality of life. The Scottish Vascular Audit Group. Eur J Vasc Endovasc Surg 1995;9:469-472

9. Khaira HS, Hanger R, Shearman CP. QOL in patients with intermittent claudication. Eur J Vasc Endovasc Surg 1996;11:65-69

10. Breek JC, Aquarius AEAM, De Vries J, Hamming JF, Van Berge Henegouwen DP. Quality of life in patients with intermittent claudication using the World Health Organisation (WHO) questionnaire. Eur J Vasc Endovasc Surg: 2001;21:118-122

11. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-1409

12. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University;1995

13. De Vries J. Beyond health status: Construction and validation of the Dutch WHO Quality of Life assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

14. WHOQOL group. The WHOQOL assessment. (WHOQOL: Development and generic psychometric properties). Soc Sci Med 1998;46:1569-1585

15. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

16. De Vries J, Van Heck GL. The World Health Organisation Quality of Life assessment instrument (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

17. Barletta G, Perna S, Sabba C, Catalano A, O'Boyle C, Brevetti G. Quality of life in patients with intermittent claudication: relationship with laboratory exercise performance. Vasc Med 1996;1(1):3-7

18. Hooi JD, Stoffers HE, Knottnerus JA, Van Re JW. The prognosis of non-critical limb ischaemia: a systematic review of population based evidence. Br J Gen Pract 1999;49:49-55

19. Kannel WB. Risk factors for atherosclerotic cardiovascular outcomes in different arterial territories. J Cardiovasc Risk 1994;1(4):33-339

20. Simonsick EM, Guralnik JM, Hennekens CH, Wallace RB, Ostfeld AM. Intermittent claudication and subsequent cardiovascular disease in the elderly. J Gerontol A Biol Sci Med Sci 1995;50A:M17-22

21. Feinglass J, McCarthy WJ, Slavensky R, Manheim LM, Martin GJ. Effect of lower extremity blood pressure on physical functioning in patients who have intermittent claudication. J Vasc Surg 1996;24:503-512

22. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain: a meta-analysis. JAMA 1995;274:9750-980

23. Robeer, GG, Brandsma JW, Van den Heuvel SP, Smit B, Oostendorp RA, Wittens CH. Exercise therapy for intermittent claudication: A review of the quality of randomised clinical trials and evaluation of predictive factors. Eur J Vasc Endovasc Surg 1998;15:36-43

24. Cook TA, O'Regan M, Galland RB. QOL following PTA for claudication. Eur J Vasc Endovasc Surg 1996;11:191-194

25. Chetter IC, Sparks JI, Scott JA, Kester RC. Does angioplasty improve the quality of life for claudicants ? A prospective study. Ann Vasc Surg 1999;13:93-103

26. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Randomised controlled trial of percutaneous transluminal angioplasty for intermittent claudication. Eur J Vasc Endovasc Surg 1996;12:167-172

27. Cook TA, Galland RB. Quality of life changes after angioplasty for claudication: medium-term results affected by comorbid conditions. Cardiovasc Surg 1997:5:424-426

28. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Is intermittent claudication improved by PTA? A randomised controlled trial. J Vasc Surg 1997;26:551-557

CHAPTER 7

EFFECTS OF CONSERVATIVE TREATMENT ON QUALITY OF LIFE, HEALTH STATUS, AND WALKING CAPACITY IN PATIENTS WITH INTERMITTENT CLAUDICATION

J.C. Breek
J. de Vries*
G.L. van Heck*
D.P. van Berge Henegouwen**
J.F. Hamming**

Dept. of Surgery, Martini Hospital Groningen, The Netherlands
Dept. of Psychology and Health, Tilburg University, Tilburg, The Netherlands *
Dept. of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands **

Submitted

ABSTRACT

Objective: To measure the effects of conservative treatment on quality of life (QOL) and health status in patients with intermittent claudication (IC).

Design: A prospective study in the vascular outpatient clinic of a teaching hospital.

Material and methods: In addition to the pain free walking distance (PFWD) and maximum walking distance (MWD) on a treadmill, QOL and health status were assessed with the WHOQOL-100 and the RAND-36 in 76 patients with IC, at study entrance and after six and 12 months of conservative treatment. Treatment consisted of the advice to stop smoking, to start non-supervised exercise training, and anti-platelet medication. Paired t-tests were used to test for changes in QOL, health status, and walking distances within the patient group. Differences compared with samples of age and sex-matched healthy persons were tested with Mann-Whitney-U tests.

Results: PFWD and MWD improved significantly in the first six months. At baseline, most aspects of QOL and health status were significantly worse compared with healthy persons. During follow-up, the recorded QOL improved with regard to the facets Pain and discomfort and Mobility. Psychological effects became apparent with a decline in both positive and negative feelings. Health status improved only with regard to Bodily pain, approaching the level of healthy controls. No significant changes in QOL, health status, or walking distances were recorded between six and 12 months follow-up.

Conclusion: Conservative treatment resulted in improved walking, better mobility, and less pain after the first six months without further improvement thereafter. However, QOL and health status remained broadly impaired in patients with IC after 12 months. Apparently, QOL and health status impairments can only partially be attributed to the walking problem. To improve QOL and health status, health care providers should supplement efforts to improve walking with care for other health- and non-health-related aspects of life that are relevant to patients with IC.

INTRODUCTION

Intermittent claudication (IC) is a common expression of peripheral arterial occlusive disease (PAOD), caused by atherosclerosis, with a benign character for the legs, but important risks of fatal cardiac and cerebrovascular events[1,2]. The disease has a detrimental impact on a wide range of aspects of daily life, as reflected in health status and quality of life (QOL)[3,4]. Since atherosclerosis is incurable, relief of complaints is the best to be achieved. Therefore, the preservation and improvement of QOL and health status have been recommended as guidelines for treatment policy in vascular disease[5,6]. Several reports have highlighted the effects of percutaneous transluminal angioplasty (PTA) and bypass surgery on health status in claudicants[7-10]. However, there is convincing evidence that, compared with invasive treatment, the results of conservative treatment in patients with IC is equally effective with regard to walking ability and health status[11-15]. Since conservative treatment is the first option for patients with IC, it is our aim to measure its effects on QOL, health status, and walking ability in a one-year prospective follow-up study.

MATERIAL AND METHODS

Patients

Between January 1999 and June 2000, QOL and health status were assessed at the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands, in all patients presenting with IC and agreeing to participate in the study by informed consent. The study was approved by the hospital's medico-ethical commission. IC was suspected on history and physical examination in 215 patients and was confirmed by treadmill performance and ankle blood pressure in 207 patients. Seven patients refused or were not capable to participate. Apart from demented, blind, and deaf patients, no one was excluded from the study. Fifty-two patients were treated primarily by PTA or bypass surgery. Initial conservative treatment was changed to PTA or surgery because of progression to incapacitating IC in 19 patients and deterioration to critical ischaemia in nine patients. Failure to complete the questionnaires or inappropriate intervals were the reasons that complete QOL and health status data could be obtained from 76 of 120 patients that were treated conservatively for at least one year. There were 57 men and 19 women with a mean age of 65 years (range 46-82 years). The treadmill pain free walking distance (PFWD), maximum walking distance (MWD), and ankle-brachial pressure indices (ABPI) were recorded. The presence and the severity of risk factors and comorbidity were recorded according to the recommended standards for reports dealing with lower extremity ischaemia (Table 1)[16].

Table 1
Distribution of risk factors and comorbidity, specified into "none", "mild", "moderate" and "severe", according to the SVS/ISCVS, in 76 patients with IC studied for health status and quality of life

	none	mild	moderate	severe
Diabetes mellitus	67 (88%)	3 (4%)	5 (7%)	1 (1%)
Tobacco use	10 (13%)	23 (30%)	22 (29%)	21 (28%)
Hypertension	43 (57%)	15 (20%)	12 (16%)	6 (8%)
Hyperlipidaemia	42 (55%)	14 (18%)	7 (9%)	13 (17%)
Cardiac status	49 (64%)	16 (21%)	10 (13%)	1 (1%)
Carotid status	65 (86%)	3 (4%)	5 (7%)	3 (4%)
Renal status	71 (93%)	1 (1%)	3 (4%)	1 (1%)
Pulmonary status	70 (92%)	5 (7%)	0 (0%)	1 (1%)

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity: see Appendix III

All patients were treated conservatively according to Housley's paradigm "stop smoking and keep walking"[17]. Patients received instruction leaflets for exercise training, but supervised programs were not provided. Unless using oral anticoagulants, all patients received anti-platelet medication for the secondary prevention of atherosclerotic events and were referred to the department of internal medicine for modification of risk factors and treatment of comorbidity. Treadmill tests, ABPI recordings, QOL, and health status assessments were performed at first presentation and after six and 12 months. At the same time, patients were asked about their smoking habits. To put the scores into perspective, the patients' results were compared with those of two groups of age and sex matched healthy persons for QOL and health status (both groups, n = 76).

Measures

QOL was assessed using the World Health Organisation Quality of Life Assessment Instrument-100 (WHOQOL-100)[18-20]. This is a generic, multidimensional, self-report QOL measure that is easy to score. It has been used in a variety of patient populations, most recently in IC[4,21]. The instrument has been developed simultaneously and cross-culturally in 15 centres around the world. In a preceding pilot-study the instrument was reduced for PAOD patients to 16 relevant facets covering the domains Physical health, Psychological health, Level of independence, Social relationships, and Environment and the generic evaluative facet Overall QOL and general health[21](see chapter 3). Each facet is represented by four questions, reflecting functional limitations and the respondent's personal evaluation of these limitations (How satisfied ..?, How much bothered ..?). The responses are expressed in 5-point scales. Scores on each facet and domain can range from 4 to 20. The reliability, validity, and sensitivity of the instrument are high[22,23]. Health status was measured with the RAND-36[24,25], which is practically identical to the Medical Outcome Study/Short Form-36 (SF-36)[26], a 36-item generic

measure. It assesses eight dimensions of health: Physical functioning, Social functioning, Limitations in usual role activities due to physical problems (Role physical), Limitations in usual role activities due to emotional problems (Role emotional), Mental health, Vitality, Bodily pain, and General health perception. In addition, Health changes over the last year are assessed. Beside scores for each subscale, the testing yields a composite health status score on a scale from 0 (worst) to 100 (best). The RAND-/SF-36 has been widely used in patients with IC. It has good reliability and validity[27] and has been recommended in patients with PAOD[6, 28, 29].
The scores of the matched controls were collected from the WHOQOL database of the department of Psychology and Health of Tilburg University, Tilburg, The Netherlands, and from the RAND-36 database of the Northern Centre for Health Care Research, Groningen, The Netherlands.

Statistics

The walking distances, QOL, and health status data are expressed in terms of mean values and standard deviations. Paired t-tests were used to detect statistically significant differences within the patient group during follow-up. Changes between patients and healthy controls were analysed with Mann-Whitney U-tests. A probability value of less than 0.05 was considered to be statistically significant.

RESULTS

Clinical indicators

Compared with baseline performance, significant improvements in mean PFWD and mean MWD were recorded after six months (Table 2). Between six and 12 months after baseline measurement, no further significant changes were recorded. The mean ABPI did not change significantly over the 12 months period. The initial 43% of the patients who indicated to smoke remained constant with 42% and 44% smoking after six and twelve months, respectively.

Table 2
Treadmill walking distances and ankle-brachial pressure indices before, and after six and twelve months of conservative treatment in 76 patients with intermittent claudication

	baseline mean (sd)	6 months mean (sd)	12 months mean (sd)
PFWD	124 (146)	287 (306)*	321 (313)*
MWD	434 (354)	560 (372)*	580 (380)*
ABPI	0.62 (0.15)	0.64 (0.13)	0.64 (0.14)

PFWD = pain free walking distance, MWD = maximum walking distance, ABPI = ankle-brachial pressure index, sd = standard deviation. Distances in meters. * Statistically significant difference ($P < 0.05$) compared with baseline. Treadmill: 3,5 km/h on a 5% incline with a maximum of 1000 m.

Quality of life

At baseline, patients' WHOQOL scores were significantly worse than those of sex- and age-matched healthy controls on the facets Overall QOL and general health, Negative feelings, Opportunities for acquiring new information and skills, Recreation and leisure, and the domains Physical health and Level of independence (Table 3). Compared with healthy persons and baseline results, the scores for the facets Positive feelings, Self-esteem, Sexual activity, and the domain Social relationships had decreased significantly after six months. During this interval, scores on the facet Mobility improved significantly. Between six and 12 months no significant QOL changes occurred. After 12 months, the scores for the facets Pain and discomfort and Mobility were significantly better than at baseline, although still worse than in healthy controls. The initial excess of Negative feelings, as indicated by the claudicants at baseline and at six months, decreased to a non-significant difference with healthy controls at 12 months.

Health status

The RAND-36 baseline scores of the patients with IC were significantly worse than those of healthy controls on all domains, except Vitality and General health (Table 4). After six months of conservative treatment, the scores for Bodily pain had improved significantly, while those for General health had declined. Nevertheless, patients indicated a significant positive Health change. Between six and 12 months, General health scores restored, but remained worse than in healthy controls. After 12 months, the scores for Bodily pain remained significantly better than at baseline and the initial difference with healthy persons at baseline disappeared. The scores for Vitality were comparable with those of the controls at all assessments.

DISCUSSION

Encouraging exercise training and life style advice resulted in a substantial better walking performance after six months, which persisted at 12 months. This clinical benefit translated into better scores for the WHOQOL facets Pain and discomfort and Mobility. The QOL decrease in Positive feelings, Self-esteem, and Sexual activity, and the temporary drop in RAND-36 General health illustrate the psychological effects of disease impact and the notion to be a patient suffering from an incurable disease. The psychological adaptation to the new situation is reflected in a slow QOL decline of Negative feelings to the level of healthy controls, and a partial restoration of the RAND-36 General health score at 12 months.
Health status remained significantly impaired after one year of conservative treatment with the exception of Bodily pain scores that returned to a non-diseased level.

Table 3
Scores on the reduced WHOQOL-100 domains and facets in 76 patients treated conservatively for intermittent claudication

	healthy controls	patients baseline	patients 6 months	patients 12 months	P
- Overall QOL and general health	16.0 (2.5)	14.4 (2.9)*	14.1 (2.6)*	14.2 (2.7)*	ns[a,b]
Physical health	15.4 (2.2)	13.6 (2.3)*	13.7 (2.5)*	13.7 (2.6)*	ns[a,b]
- Pain and discomfort	9.1 (2.4)	12.0 (2.7)*	11.6 (2.9)*	11.2 (2.9)*	.015[b]
- Energy and fatigue	15.3 (3.0)	13.1 (2.9)*	12.9 (3.2)*	12.8 (3.1)*	ns[a,b]
- Sleep and rest	16.1(3.6)	15.8 (3.8)	15.7 (4.1)	15.6 (4.1)	ns[a,b]
Psychological health	-	-	-	-	
- Positive feelings	14.5 (2.1)	13.9 (2.4)	13.3 (2.2)*	13.4 (2.3)*	.019[a]
- Thinking, learning, memory and concentration	-	-	-	-	
- Self-esteem	14.6 (2.6)	14.3 (2.8)	13.7 (2.2)*	14.0 (2.2)	.009[a]
- Body image and appearance	-	-	-	-	
- Negative feelings	8.8 (2.9)	10.2 (3.2)*	10.0 (2.7)*	9.9 (3.2)	ns[a,b]
Level of independence	16.7 (2.6)	13.4 (2.7)*	13.5 (2.9)*	13.4 (3.0)*	ns[a,b]
- Mobility	16.9 (3.1)	11.9 (2.7)*	12.9 (3.3)*	12.8 (3.1)*	.007[a,b]
- Activities of daily living	16.4 (2.9)	14.3 (3.1)*	14.0 (3.0)*	14.1 (2.8)*	ns[a,b]
- Dependence on medication and treatments	6.9 (3.2)	10.3 (3.5)*	10.5 (3.6)*	10.5 (3.7)*	ns[a,b]
- Working capacity	16.4 (3.0)	13.6 (3.8)*	13.4 (3.9)*	13.2 (3.9)*	ns[a,b]
Social relationships	15.2 (2.5)	14.9 (2.8)	14.3 (2.1)*	14.2 (2.0)*	.043[a] .005[b]
- Personal relationships	15.6 (2.4)	16.2 (3.1)	15.8 (2.7)	15.7 (2.4)	ns[a,b]
- Social support	-	-	-	-	
- Sexual activity	14.4 (3.6)	13.3 (3.5)	12.5 (3.3)*	12.5 (3.0)*	.035[a] .019[b]
Environment	-	-	-	-	
- Physical safety and security	-	-	-	-	
- Home environment	16.2 (2.3)	16.0 (2.8)	15.4 (2.7)	15.6 (2.4)	ns[a,b]
- Financial resources	-	-	-	-	
- Health and social care	-	-	-		
- Opportunities for acquiring new information and skills	16.0 (2.5)	14.4 (2.6)*	14.4 (2.5)*	14.3 (2.7)*	ns[a,b]
- Participation in and opportunities for recreation/leisure	16.0 (2.8)	14.5 (3.2)*	14.6 (3.0)*	14.2 (2.9)*	ns[a,b]
- Physical environment	-	-	-	-	
- Transport	17.6 (2.6)	16.5 (3.5)	16.7 (3.5)	16.4 (3.1)	ns[a,b]
Spirituality, religion, pers. beliefs	-	-	-	-	

Data are presented in terms of means and standard deviations. The scores on the facets Pain and discomfort, Negative feelings and Dependence on medication and treatments are inverse. High scores reflect low QOL.
ns = not significant. * = statistically significant difference between healthy persons and patients ($P < 0.05$).
a = P-value for the difference between baseline and 6 months scores.
b = P-value for the difference between baseline and 12 months scores.

Table 4
Scores on the RAND-36 domains in 76 patients treated conservatively for intermittent claudication

	healthy controls	patients baseline	patients 6 months	patients 12months	Significance
Physical functioning	67.6 (29.8)	54.5 (18.8)*	58.1 (23.0)*	60.5 (24.9)*	ns[a,b,c]
Social functioning	84.7 (23.0)	73.3 (26.3)*	74.6 (24.5)*	74.3 (26.0)*	ns[a,b,c]
Role physical	74.0 (39.2)	52.4 (43.0)*	58.7 (40.0)*	54.1 (43.3)*	ns[a,b,c]
Role emotional	87.7 (26.4)	72.8 (39.1)*	79.1 (83.3)*	64.9 (40.8)*	ns[a,b,c]
Mental health	76.5 (17.0)	70.0 (18.7)*	69.2 (16.0)*	70.4 (19.3)*	ns[a,b,c]
Vitality	63.2 (22.6)	59.5 (21.5)	58.9 (20.8)	60.1 (19.0)	ns[a,b,c]
Bodily pain	75.7 (26.7)	58.8 (21.2)*	68.7 (19.7)*	70.2 (21.4)	P < .001[a] P < .001[b]
General health	62.6 (24.9)	58.0 (19.8)	50.8 (18.4)*	55.7 (17.3)*	P = .002[a] P = .008[c]
Health change	50.0 (22.7)	35.4 (20.0)*	46.2 (26.0)	46.4 (24.0)	P = .001[a] P = .001[b]

Data are presented in terms of means and standard deviations. ns: not significant
* = statistically significant difference between healthy persons and patients ($P < 0.05$).
a = P-value for the difference between baseline and 6 months scores.
b = P-value for the difference between baseline and 12 months scores.
c = P-value for the difference between 6 and 12 months scores.

Surprisingly, better walking, which would seem to be an essential aspect for patients with IC, did not translate into better Physical functioning as measured with the RAND-36. This might be explained by the questions of this domain that rather ask about restrictions to perform activities of various intensity than evaluate walking abilities. In contrast, QOL measurement did show significantly better scores for the WHOQOL facet Mobility after six and 12 months, which illustrates the complementary value of subjective appraisal of functioning compared with mere recording of functional limitations as in health status.

The present findings with respect to QOL and health status are in contrast with those of Currie et al. who found no effects at all following non-supervised exercise training[7]. Some studies showed minimal effects of conservative treatment[10,32], whereas Pell et al. described a further deterioration of health status[33]. Differences in size of the patient groups, measures that were used, compliance with the regimen, and duration of follow-up might be responsible for the divergent outcomes. The modest effects on QOL and health status in the present study are in contrast with the successful treatment in terms of walking performance. This is in concordance with the finding that, in addition to the walking impairment, cardiovascular risk factors and comorbidity have a major impact on QOL in patients with IC[4]. Moreover, it has been shown that the clinical indicators of IC have a weak or no relationship with health status and QOL[34,35], or only with certain aspects like Mobility[4] and Physical Functioning[9,36].

Despite the fact that patients walked longer, recorded less pain (health status), experienced less problems as a result of pain (QOL), and perceived a better mobility, most aspects of

QOL and health status were unaffected by the walking benefits and remained significantly worse than in healthy persons. This means that the QOL and health status benefits of improved walking following conservative treatment are limited to pain and mobility. Consequently, to focus on walking improvement only might be the wrong target to aim, if QOL and health status are considered the main goals of treatment. In other words, patients with IC may be treated successfully with respect to the walking impairment, but the concurrent QOL and health status effects are limited. Since QOL is increasingly recommended as the goal of treatment in patients with IC, it should be realised that current treatment options for patients with IC are insufficient with respect to most of the QOL impairments.

The persistent smoking habits as recorded suggest that a simple advise to stop smoking is not enough and active support should be added to increase the effects of conservative treatment.

Although no further improvements were recorded after six months, the initial effects of conservative treatment on walking, QOL, and health status persisted for at least six additional months. The practical implication of this finding may be that patients who attain an acceptable walking distance, QOL, and health status after six months of conservative treatment should be encouraged to continue exercise training. Patients who do not experience sufficient improvements after six months of conservative treatment are unlikely to benefit from this form of treatment. As a consequence, invasive therapy may become the next treatment option in these patients. However, if treatment aims not only to improve walking, but also QOL of patients with IC, attention for risk factors and comorbidity, and psychological and social support to accommodate with the impairments that are not relieved by better walking may offer important benefits.

REFERENCES

1. Dormandy J, Heeck L, Vig S. The natural history of claudication: Risk to life and limb. Sem Vasc Surg 1999:12:123-137

2. Dormandy J, Heeck L, Vig S. Lower extremity arteriosclerosis as a reflection of a systemic process: Implications for concomitant coronary and carotid disease. Sem Vasc Surg 1999;12:118-122

3. Pell JP. Impact of intermittent claudication on QOL. Eur J Vasc Endovasc Surg 1995;9:469-472

4. Breek JC, Hamming JF, De Vries J, Aquarius AE, Van Berge Henegouwen DP. Quality of life in patients with intermittent claudication using the World Health Organisation (WHO) questionnaire. Eur J Vasc Endovasc Surg 2001;21:118-22

5. Chetter IC, Scott DJA, Kester RC. An introduction to QOL analysis: The new outcome measure in vascular surgery. Eur J Vasc Endovasc Surg 1998;15:4-6

6. TASC working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

7. Currie IC, Wilson YG, Baird RN, Lamont PM. Treatment of intermittent claudication: The impact on quality of life. Eur J Vasc Endovasc Surg 1995;10:356-361

8. Chetter IC, Sparks JI, Scott JA, Kester RC. Does angioplasty improve the QOL for claudicants? A prospective study. Ann Vasc Surg 1999;13:93-103

9. Feinglass J, McCarthy WJ, Slavensky R, Manheim LM, Martin GJ and the Chicago Claudication Outcomes Group. Effect of lower extremity blood pressure on physical functioning in patients who have intermittent claudication. J Vasc Surg 1996;24:503-512

10. Taft C, Karlsson J, Gelin J. et al. Treatment efficacy of intermittent claudication by invasive therapy, supervised physical exercise training compared to no treatment in unselected randomised patients II: One year results of health-related quality of life Eur J Vasc Endovasc Surg 2001 ;22 :114-123

11. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain. A meta-analysis. JAMA 1995;274:975-980

12. Perkins JMT, Collin J, Creasy TS, Fletcher EWL, Morris PJ. Exercise training versus angioplasty for stable claudication. Long and medium term results of a prospective randomised trial. Eur J Vasc Surg 1996;11:409-413

13. Robeer, GG, Brandsma JW, Van den Heuvel SP, Smit B, Oostendorp RA, Wittens CH. Exercise therapy for intermittent claudication: A review of the quality of randomised clinical trials and evaluation of predictive factors. Eur J Vasc Endovasc Surg 1998;15:36-43

14. Cook TA, Galland RB. Quality of life changes after angioplasty for claudication: Medium-term results affected by comorbid conditions. Cardiovasc Surg 1997:5:424-426

15. Whyman MR, Fowkes FGR, Kerracher EMG. et al. Is intermittent claudication improved by PTA? A randomised controlled trial. J Vasc Surg 1997;26:551-557

16. Rutherford RB, Baker JD, Ernst C. et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg 1997;26:517-538.

17. Housley E. Treating claudication in five words. Br Med J (Clin Res Ed) 1988 May 28;296(6635):1483-4

18. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-1409

19. De Vries J, Van Heck GL. Nederlandse WHOQOL-100 [Dutch WHOQOL-100]. Tilburg: Tilburg University; 1995

20. De Vries J. Beyond health status. Construction and validation of the Dutch WHO Quality of Life Assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

21. Breek JC, Hamming JF, De Vries J, Van Berge Henegouwen DP, Van Heck GL. The impact of walking impairment, cardiovascular risk factors, and comorbidity on the quality of life in patients with intermittent claudication. J Vasc Surg 2002;36:94-99

22. De Vries J, Van Heck GL. The World Health Organization Quality of Life assessment (WHOQOL-100): Validation study with the Dutch version. Eur J Psychol Assessment 1997;13:164-178

23. O'Carroll RE, Cossar JA, Couston MC, Hayes PC. Sensitivity to change following liver transplantation: A comparison of three instruments that measure quality of life. J Health Psychol 2000;5:69-74

24. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-227

25. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: A manual Groningen: Northern Centre for Health care Research; 1993

26. Ware JE, Sherbourne CD. The SF-36 Short Form health status survey 1, conceptual framework and item selection. Med Care 1992;30:473-483

27. Bowling A. Measuring disease: A review of disease-specific quality of life measurement scales. Buckingham: Open University Press;1985

28. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardization. Eur J Vasc Endovasc Surg 1997;13:597-60

29. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: Revising the paradigm for the 21st century. J Vasc Surg 2000;32:1239-1250

30. Bergner DK. Measurement of health status. Med Care 1985;23:696-704.

31. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

32. Feinglass J, McCarthy WJ, Slavensky R, Manheim LM, Martin GJ. Functional status and walking ability after lower extremity bypass grafting or angioplasty for intermittent claudication: results from a prospective outcomes study. J Vasc Surg 2000;31:93-103

33. Pell JP, Lee AJ. Impact of angioplasty and arterial reconstructive surgery on the quality of life of claudicants. The Scottish Vascular Audit Group. Scott Med J 1997;42:47-48

34. Chetter IC, Dolan P, Spark JI, Scott DJA, Kester RC. Correlating clinical indicators of lower limb ischaemia with quality of life. Cardiovasc Surg 1997;5:361-366

35. Klevsgard R, Hallberg IR, Risberg B, Thomsen MB. Quality of life associated with varying degrees of chronic lower limb ischaemia: Comparison with a healthy sample. Eur J Vasc Endovasc Surg 1999;17:319-325

36. Barletta G, Perna S, Sabba C, Catalano A, O'Boyle C, Brevetti G. QOL in pts with intermittent claudication: Relationship with laboratory exercise performance. Vasc Medicine 1996;1:3-7

CHAPTER 8

GENERAL DISCUSSION

Traditionally, treatment efforts for patients with intermittent claudication (IC) have focused on improvement of the walking distance. This seems rational with respect to the presenting complaint, although the choice of therapy for individual patients may not always be evident. The main problem is to find a balance between the patient's perception of disease, the importance of additional manifestations of atherosclerosis and other comorbidity, and treatment possibilities. In the past, little attention has been paid to subjective outcome measures. However, in recent years, quality of life (QOL) assessment has been recommended repetitively to supplement the imperfections of current management protocols for patients with IC[1-5]. Several attempts have been made to meet this recommendation. Because the term "QOL" has been used for different concepts – reports on QOL often concern health status – study results, obtained with a variety of instruments, are difficult to interpret and compare. Health status usually expresses more or less objective assessments of functioning, which is often erroneously equated with good or bad QOL. Studies in which low levels of functioning were paralleled by high-perceived QOL show that the one does not exclude the other[6,7]. This means that for the assessment of QOL, the individual perception of disease and treatment not only should be *recorded*, but also be *evaluated* by the patient. The World Health Organisation (WHO) has defined QOL with an emphasis on subjective evaluation of functioning and has instigated the development of a transcultural assessment instrument, the WHO Quality of Life Assessment instrument-100 (WHOQOL-100)[8,9]. In the present study, the Dutch version of this instrument[10] was used in patients with IC, who were referred to the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands, at first presentation and after a period of conservative treatment. Health status was assessed with the RAND-36[11,12], as recommended by the international vascular societies[4,5,13]. Besides, the importance of walking impairment, usual risk factors, and comorbidity for the QOL of patients with IC was studied. The results show that IC has a broad impact on QOL as defined by the WHO, that the walking problem is only of relative importance, and that comorbidity has a major impact on QOL. Conservative treatment appeared beneficial with regard to walking, mobility, and pain, but QOL and health status on the whole remained substantially worse than in healthy controls.

CRITICAL REMARKS

How should a doctor approach the problem for which the patient consults him/her in daily practice? According to the findings of this study, the patient's question for treatment of a walking problem might almost be put aside. There are valid arguments to do nothing with respect to the occluded blood vessels, and tell patients to walk (which they can not, due to IC) and to live a healthier life (which, for a long time, they have not been able to). Inadvertently, the initial demand for relief of symptoms has started a process to prevent further deterioration of a systemic disease. Is this attitude fair to the patient? Does it appreciate individual subjective QOL? With regard to the atherosclerotic threats to longevity,

the answer is affirmative. However, the presenting symptom should not be disregarded in view of the serious systemic complications of atherosclerosis. Because patients with IC demand and will appreciate relief of their symptoms, efforts to improve walking, after adequate modification of risk factors and treatment of concomitant disease, should be tailored to the level of the individual patient, taking account of personal abilities, needs, expectations, and the physical situation. As has been shown in chapter 7, a single advice to stop smoking is not effective, but repeated encouragement may have better results[14]. Similarly, exercise training may be optimised with regular support[15]. A "frapper toujours" approach towards conservative treatment of patients with IC seems attractive, but will only succeed with the help of family doctors and specialised supportive staff, and not in the last place partners, family, and friends. A network close to the claudicant may be more adequate to provide support on a day-to-day basis than a short hospital visit once or twice a year. This means that claudicants who have been evaluated and treated for risk factors and concomitant disease, and who respond well to conservative treatment should be discharged from clinical follow-up.

DRAWBACKS OF THE STUDY AND QUESTIONS TO BE ANSWERED

QOL scores have no units, like distances and weights, and can only be compared with themselves. There are no "normal values" for QOL. However, extreme scores within a study population indicate discrepancies from the average or "norm scores". Such sizeable deviations of the mean scores of a healthy population are indicative for much better or worse QOL. Summing scores from more than one person, however, eliminates individual values and produces a distorted perspective of a non-existent average person, as pointed out by Hunt[16]. Except for the follow-up study in which paired t-tests were used, all results and conclusions in this study are based on the mean scores of patients and healthy controls. Since individual variations are essential for QOL, a reserved attitude should be adopted towards (these) scores that do not exclusively represent individual QOL[17]. Unfortunately, individual QOL at baseline can only be estimated against means from reference groups. The efficacy of treatment with regard to an individual's QOL can more reliably be assessed by comparing post-intervention scores with individual baseline scores.

It can be debated whether the recorded QOL improvements can be attributed to unsupervised exercise training or even are related to improved walking at all. Response shift, which means that the terms of reference by which QOL is judged change over time, may account for at least some of the improvements. Because QOL varies not only between individuals, but also within individuals across, success of treatment can also be explained by a downward adjustment of wishes and expectations[18-20]. In that case, improvements would not have to be less important from a patient's point of view, for it should be kept in mind that the recorded QOL and health status improvements were obtained from the patients themselves. The up and

down movement of health status and QOL scores during follow-up reflect adaptation to the notion of being a patient and may be regarded as an illustration of this phenomenon.
A difficult situation emerges if a self-confident patient makes the trade-off between risks to life and comfort of walking, i.e. quantity versus quality of life. A demand for invasive therapy to improve walking may be beneficial for QOL, though at the cost of a few years life expectancy if smoking and other unhealthy behaviour persist. For clinical relevance, the goals of treatment should agree with the goals of the patient. Yet, the methods to achieve the goals should be acceptable - the end does not justify the means - and the results of treatment should be relevant for the patient[21]. Persuasiveness and understanding of both parties are required to serve functional improvement and future deterioration.
Based on the findings of this study, is seems reasonable to start with (unsupervised) exercise training for six months in almost every patient with IC. It should be noted, however, that conservative treatment in this study mainly consisted of doing nothing in the expectation that the patient would start and proceed with exercise training. This policy probably comes close to the natural course of IC. The possible benefits of a structured supervised exercise program were not examined. Supervised exercise programs proved to be superior to non-supervised programs with regard to walking performance, patient reported walking ability, and physical functioning[22,23]. However, Patterson et al. in a study comparing supervised and home based exercise programs concluded that a supervised program resulted in optimal walking benefits, but a structured home-based program provided similar functional improvement and might be a satisfactory alternative for patients with lesser walking requirements[24].
This study reported on the importance of walking, risk factors, and comorbidity for QOL in patients with IC. In order to tailor treatment advice, it is relevant to know more about the predictive value of patient characteristics for the response to treatment. In other words, which patients can be expected to improve after some form of treatment, and which cannot? Several studies on patients with critical limb ischemia have shown that the preoperative functional level and the patients' perception of functional status, health status, and well-being at baseline are independent predictors of improved function and well-being after revascularisation, even in the very elderly[25-28]. The predictive value of patient characteristics for treatment results may also contribute to a better treatment advice for claudicants. Since the present study does not provide this information, a prospective study on this topic is required.

FUTURE PROSPECTS, FURTHER STUDY, AND PRACTICAL CONSIDERATIONS

It is still too early for the wide implementation of QOL assessment in the clinical management of patients with IC. A lot of missionary work has to be done to convince the medical community of the value of QOL assessment for the benefit of both the patient and the doctor[29]. Considering the gap between the traditional parameters for rating the severity of IC and patient values, it seems no longer acceptable to exclude the latter from clinical practice. However, the incorporation of QOL assessment in daily practice is a difficult and time-consuming task for which there is hardly time in a busy outpatient clinic. Still, to assess QOL in *all* patients with IC, it is necessary to develop short and simple questionnaires that are relevant to the patient group, widely recognised, and easy to score. Questionnaires can be (e-) mailed for home-completion or can be completed in the outpatient clinic, provided that the recommended facilities as mentioned in chapter 3 are met. Swift calculation methods to generate QOL profiles and reference values of different age groups, that take risk factors and comorbidity into consideration, should be available in a database to assure instant interpretation of QOL, which allows guiding treatment in a way that corresponds with a patient's wishes and expectations.

It is unnecessary to reinvent the wheel by developing disease-specific QOL measures, which tend to focus on symptoms, rather than on the underlying disease[30]. Instead, generic instruments are useful for monitoring patients with more than one condition and can be used to compare patients with different conditions[31]. Moreover, it has been advocated to adapt instruments for specific patient populations from existing validated instruments[32,33]. Regarding the discrepancy that appeared between health status and QOL in claudicants, it seems unwise to persist in measuring QOL by means of health status instruments, no matter how widely accepted, disease-specific, and validated. Only by recognising the importance of personal, subjective evaluation of functional impairments *and* appreciation of aspects of life that are not directly health-related, a picture will emerge of what is important for a patient. Starting from the results of the present study, the next step will be a comparison of the reduced PAOD version of the WHOQOL-100 with the instrument's validated short generic version, the WHOQOL-bref[34]. Subsequently, IC-specific facets can be attached to comply with particular needs of the patient population. A study on the predictive value of patient characteristics for the results of treatment should enable us to adjust treatment advice to the individual patient. Since the proof of the pudding is in the eating, a study addressing the results of treatment based on QOL assessment will reveal the real value of considering the patient's point of view in clinical decision making. However, treatment advice based on QOL assessment will always be limited by the patient's medical condition and technical possibilities.

For the management of non-physical and practical QOL limitations that are encountered in patients with IC, therapeutic options should be extended with less conventional means like psychological methods to change life style and coping abilities, and to reduce negative

feelings. Social interventions may assist to decrease problems that are experienced in leisure activities and transport. The results of a study on personality characteristics and the psychosocial context of PAOD patients are awaited to specify and support these aspects. The feasibility of such an approach that, in addition to the traditional concept of "disease and care", also takes account of the influence of individual aspects of illness through a "health and behaviour" strategy has recently been described[35]. Consequently, health care professionals with specific capabilities are needed to support conventional medical care. Physical therapists, nurse practitioners, psychologists, and social workers could contribute to improve walking, to change lifestyle and acquired behaviour, and to adjust living conditions. However, the transfer of non-medical tasks to other disciplines should not increase therapeutic efforts and financial burden, but rather optimise treatment and reduce pressure on surgical staff and hospital facilities. For, patients who are not satisfied with treatment results are unlikely to refrain from medical services, whereas satisfied patients, even in the absence of objective change in functional abilities, may become comfortable with their situation and the way they have learned to live with limitations. Such an enterprise can only be successful and mutual beneficial if academic and peripheral hospitals, social faculties, general practitioners, patient organisations, and health insurance authorities collaborate.

CONCLUSION AND FINAL REMARKS

What does the present study add to the available knowledge on QOL in patients with IC and what recommendations can be made?

- For the first time, QOL, as defined by the WHO, has been measured in claudicants. As a result, a set of baseline QOL data for patients with IC is available now.
- The study provides an insight into the predictive value of walking limitation, cardiovascular risk factors, and comorbidity for QOL in patients with IC.
- The results of a comparison between health status and QOL in patients with IC stress the importance of subjective evaluation in addition to mere functional assessment for understanding and interpreting the influence of IC on patients' daily life.
- The effects of conservative treatment on walking capacity, QOL, and health status emerge in the first six months. Effects are limited to mobility and pain. Compared with healthy persons, QOL and health status on the whole remain broadly impaired.

The present study is the first to report on QOL, as defined by the WHO, in patients with IC. This means that the findings should be interpreted with caution, because a study can only be appreciated if the results are reproducible. Based on these findings, it seems premature to deduce definite guidelines. Nevertheless, the following suggestions can be made:

- The WHOQOL-100 should be further shortened and adapted, comprising disease-specific aspects, to assist in clinical decision making for patients with IC.
- Considering the relative importance of the walking limitation and the overwhelming impact of comorbidity on QOL in patients with IC, a reserved attitude towards invasive treatment is justified.
- Subjective evaluation of functional impairments should be directive in clinical decision making in all patients with IC.
- Patients who attain an acceptable level of performance, physical, psychological, and social functioning, objectively and according to their own standards and expectations after six months of unsupervised exercise training, should be encouraged to continue.
- Patients who consider treatment results to be insufficient after six months have an indication for invasive treatment, provided that there are no medical contraindications or objections with regard to QOL.

Future studies, as outlined above, should contribute to a better understanding of the interaction between disease, functional impairments, repercussions on QOL and health status, psychosocial context, and patient characteristics. Unravelling this highly individual network of interdependent variables will help to extend efforts for optimising the quality of care for patients with IC.

REFERENCES

1. Joyce CRB. Health status and quality of life: Which matters to the patient? J Cardiovasc Pharmacol 1994;23(suppl.3):S26-S33

2. Rauwerda JA, Kasteleijn DGA, Van Oosterhout MJW. In: Vaatpatiënten in beeld. Hoofdstuk 2: Aanbeveling. Nederlandse Hartstichting, Den Haag, 1998

3. Golledge J, Garrat A, Greenhalgh RM, Davies AH. Patient-assessed health outcome in peripheral arterial disease. Eur J Vasc Endovasc Surg 2000;19:109-110

4. McDaniel MD, Nehler MR, Santilli SM. et al. Extended outcome assessment in the care of vascular diseases: revising the paradigm for the 21st century. J Vasc Surg 2000;32(6):1239-50

5. TASC working group. Treatment of intermittent claudication. J Vasc Surg 2000;31: S77-S89

6. O'Boyle CA. The schedule for the evaluation of individual quality of life (SEIQoL). Int J Ment Health 1994;23:3-23

7. Waldron D, O'Boyle CA, Kearny M, Moriarty M, Carney D. Quality of life measurement in advanced cancer: Assessing the individual. J Clin Oncol 1999;17:3603-3611

8. WHOQOL group (1994). Development of the WHOQOL: Rationale and current status. Int J Ment Health 1994;23:24-56

9. WHOQOL group (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. Soc Sci Med 1995; 41:1403-1409

10. De Vries J. Beyond health status. Construction and validation of the Dutch WHO Quality of Life Assessment instrument. Doctoral dissertation. Tilburg: Tilburg University, 1996

11. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-227

12. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: A manual Groningen: Northern Centre for Health Care Research; 1993

13. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: Suggestions for European standardization. Eur J Vasc Endovasc Surg 1997;13:597-60

14. Silagy C. Physician advice for smoking cessation. Cochrane Database Syst Rev. 2000;(2):CD000165

15. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain. A meta-analysis. JAMA 1995 Sep 27;274(12):975-80

16. Hunt SM. The problem with quality of life. Qual Life Res 1997;6:205-212

17. Testa MA, Simonson DC. Assessment of quality of life outcomes. Current Concepts 1996;334:835-840

18. Allison PJ, Locker D, Feine JS. Quality of life: a dynamic construct. Soc Sci Med 1997 Jul;45(2):221-30

19. Sprangers MA, Schwartz CE. Integrating response shift into health-related quality of life research: A theoretical model. Soc Sci Med 1999 Jun;48(11):1507-15

20. Carr AJ, Bibson B, Robinson PG. Is quality of life determined by expectations or experience? BMJ 2001;322:1240-1243

21. Ogles BM, Lunne KM, Bonesteel K. Clinical significance: History, application and current practice. Clin Psych Rev 2001;21:421-446

22. Regensteiner JG, Meyer TJ, Krupski WC, Cranford LS, Hiatt WR. Hospital versus home-based exercise rehabilitation for patients with peripheral arterial occlusive disease. Angiology 1997 Apr;48(4):291-300

23. Gardner AW, Katzel LI, Sorkin JD. et al. Exercise rehabilitation improves functional outcomes and peripheral circulation in patients with intermittent claudication: A randomized controlled trial. J Am Geriatr Soc 2001 Jun;49(6):755-62

24. Patterson RB, Pinto B, Marcus B, Colucci A, Braun T, Roberts M. Value of a supervised exercise program for the therapy of arterial claudication. J Vasc Surg 1997 Feb;25(2):312-8; discussion 318-9

25. Nehler MR, Moneta GL, Edwards JM, Yeager RA, Taylor LM, Porter JM. Surgery for chronic lower limb ischemia in patients eighty or more years of age: Operative results and assessment of postoperative independence. J Vasc Surg 1993;18:18-26

26. Gibbons GW, Burgess AM, Gusdagnoli E. et al. Return to well-being and function after infrainguinal revascularisation. J Vasc Surg 1995;21:35-45

27. Abou-Zamzam AM, Lee RW, Moneta GL, Taylor LM, Porter JM. Functional outcome after infrainguinal bypass for limb salvage. J Vasc Surg 1997;25:287-297

28. Pomposelli FB, Arora S, Gibbons GW. et al. Lower extremity arterial reconstruction in the very elderly: Successful outcome preserves not only the limb but also residential status and ambulatory function. J Vasc Surg 1998;28:215-225

29. De Vries J. Quality of life assessment. In: Vingerhoets A.J.J.N. (ed.). Assessment in behavioural medicine. Hove: Brunner-Routledge, 2001

30. Fraser SCA. Quality of life measurement in surgical practice. Br J Surg 1993;80:163-169

31. Stewart AL, Greenfield S, Hays RD et al. Functional status and well-being of patients with chronic conditions. JAMA 1989;262:907-913

32. Ware JE Jr. Standards for validating health measures: Definition and content. J Chronic Dis 1987;40(6):473-80

33. Aaronson NK. Quantitative issues in health-related quality of life assessment. Health Policy 1988;10(3):217-30

34. The WHOQOL Group. Development of the World Health Organisation WHOQOL-BREF quality of life assessment. Psychol Med. 1998 May;28(3):551-8

35. Overgoor AG. Zorg en welzijn bijeen. Medisch Contact 2003;58:938-941

CHAPTER 9

SUMMARY

Atherosclerosis is an incurable disease and most patients die of cardiac or cerebrovascular complications. Peripheral arterial occlusive disease (PAOD) is caused by atherosclerosis and intermittent claudication (IC) can be a first manifestation. Treatment of IC has usually been focussed on the limited walking capacity rather than on the disease or on the patient. In spite of the risks of atherosclerosis for life expectancy and the quality of remaining life, the development of surgical techniques and interventional radiology have directed treatment of IC predominantly to the restoration of blood flow. The appropriateness of such a policy depends on the degree of the handicap, the relative impact of concomitant disease, and patient characteristics. The severity of IC and the results of treatment are traditionally expressed in terms of walking distance, ankle-brachial blood pressure indices, and patency. Since IC, above all, affects functional abilities rather than bodily integrity or life expectancy, an approach that takes account of the individual perception of illness, as a supplement to traditional clinical end-points, is of particular importance for the understanding of disease impact and the interpretation of treatment results. The current clinical parameters for the assessment of IC do not provide such information. As a consequence, the appropriateness of the traditional measures of disease impact and treatment outcome, as mentioned above, must be questioned with regard to the patients' view of illness. New methods should be developed and used to assess disease severity and impact on daily life in patients who present with IC as a symptom of PAOD. A way to assess the personal context of a patient is to use quality of life (QOL) measures. This thesis is about QOL in patients with IC and the role of risk factors and comorbidity that are inherent to this particular patient group and might influence QOL. Reports on QOL in patients with IC often concern health status rather than QOL. To avoid confusion, it is important to recognise health status as objective assessment of disease impact on physical, psychological, and social functioning. QOL, as defined by the World Health Organisation, is "an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations, standards, and concerns. It is a broad ranging concept incorporating in a complex way the individual's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment".

Chapter 2 provides a comprehensive review of the definitions of the concepts that are generally labelled as QOL, assessment instruments, and results of studies in patients with IC. The accumulated data give a picture of the broad impact of IC on daily life. Increasing IC is mainly responsible for the deterioration of physical aspects of QOL. Treatment may alleviate symptoms and improve aspects of physical functioning. However, QOL levels after treatment hardly ever approach those of a non-diseased population. The enthusiasm for measuring QOL before and after treatment in patients with IC is in contrast with the disappointing lack of reports on the incorporation of QOL measures as guidelines in clinical practice.

A pilot-study with the World Health Organisation Quality of Life Assessment instrument-100 (WHOQOL-100) was conducted in 22 patients with varying degrees of lower limb ischemia to investigate its suitability for the assessment of QOL in patients with PAOD. The instrument was chosen because the concept comes most closely to the WHO definition of QOL. Another aim was to reduce patient burden of completing the full WHOQOL-100 by limiting the instrument to aspects that provide relevant information for this particular patient group. Because of the established value of assessing health status (or health-related QOL) in patients with PAOD and the popularity of the instrument, the RAND-36 was also administered to the patients. Finally, the actual process of completing the questionnaires was studied.
Both instruments were tested, by means of parameters for response distribution and internal consistency. Because a broad range of ischemia was required to obtain a range of answers, it was decided to include patients with chronic critical and non-critical lower limb ischaemia. The results of the pilot-study, as described in chapter 3, show that the WHOQOL-100 is a satisfactory instrument for QOL assessment in PAOD patients. The instrument could be reduced to 16 out of the original 25 facets covering the domains Physical health, Psychological health, Level of independence, Social relationships, and Environment, and the generic evaluative facet Overall QOL and general health. Despite flaws with regard to the response distribution of some questions, the RAND-36 was not reduced, because it is already short and widely accepted throughout the medical community. Recommendations were made to overcome practical problems that were encountered in completing the questionnaires by predominantly elderly patients.
In the literature on QOL in patients with IC, the terms health status and QOL are often used without further explanation. In chapter 4, an attempt is made to describes similarities and differences between health status and QOL, based on data that were collected in 200 patients with IC, who completed the RAND-36 and the reduced version of the WHOQOL-100.
There was agreement between the results of both assessments with regard to physical limitations, but not for Social functioning and Pain. Patients with low scores on the RAND-36 domains Social functioning and Bodily pain not necessarily felt socially impaired or experienced pain as a major problem in daily life as indicated in the WHOQOL. QOL assessment disclosed the background of impairments in the RAND-36 domains Mental health and General health perception. The evaluation of non-health-related aspects and environmental factors, as incorporated in the WHOQOL, revealed problems that otherwise would have been missed. Based on the comparison of health status and QOL scores in patients with IC, it was concluded that subjective evaluation of QOL dimensions offers an additional value to mere recording of functional impairments. QOL assessment without taking account of the claudicants' subjective opinion may be misleading and carries the risk to direct treatment efforts at the wrong targets.

The first study (chapter 5) that addressed QOL, as defined by the WHO, in patients with IC, demonstrated a significant impact of IC on a broad range of QOL facets and domains. Patients evaluated their functioning significantly worse than healthy persons with regard to Physical health and Level of independence. In addition, patients experienced more negative feelings and reported limitations in the environmental domain. Finally, Overall QOL and general health were significantly worse than in healthy controls. The finding that increasing claudication only affected the facet Mobility suggests that successful treatment in terms of improving the walking distance may have a limited effect on QOL on the whole. The significant dependence on medication and treatments is not directly related to impaired walking and suggests a major impact of comorbidity on QOL.

This challenging finding was investigated in a study, described in chapter 6, on the predictive value of demographic variables, the severity of IC, cardiovascular risk factors and comorbidity, and the presence of non-vascular back, hip, or knee symptoms for QOL in patients with IC. Surprisingly, the presence of non-vascular joint complaints had an overwhelming predictive value for many aspects of QOL. With more concomitant diseases, patients had a worse overall QOL and general health, had lower scores for the facet Energy and fatigue, and felt more dependent on medication and treatments. The severity of IC was a statistically significant predictor of QOL for the facets Mobility, Activities of daily living and Working capacity, as well as the facets Pain and discomfort, Sexual activity, and Transport.

In conclusion, the study revealed that QOL in patients with IC is only partially determined by the severity of IC and that the importance of cardiovascular risk factors, comorbidity, and the presence of back, hip, or knee symptoms should be recognised and taken into account in the treatment policy.

The relatively modest importance of the walking problem and the significant impact of comorbidity on QOL in patients with IC seem to rationalize the reserved attitude towards invasive treatment, as currently recommended. To explore the effects on QOL, health status, and walking capacity, a follow-up study was performed in patients, who were treated conservatively (chapter 7). After a year of the most basic form of conservative treatment, i.e., Housley's principle "stop smoking and keep walking", walking performance improved significantly. Improvements with regard to the facets Mobility and Pain and discomfort (reduced WHOQOL) and Bodily pain (RAND-36) paralleled the walking benefits. It was remarkable that the changes in walking capacity, QOL, and health status all took place in the first six months, and remained at that level for at least six additional months. To get an impression of the relative importance of QOL and health status changes, scores were compared with those of age and sex-matched healthy persons. QOL scores did not reach the level of healthy controls, but conversely dropped significantly for the facet Positive feelings after six and 12 months, compared with healthy controls. The initial excess of negative feelings in patients with IC gradually decreased to a level that compared with healthy

controls. After a year, RAND-36 Bodily pain scores approached the level of healthy individuals. Despite improved walking, QOL and health status remained largely impaired after one year of conservative treatment, confirming the conclusions in chapters 5 and 6 that QOL impairments in patients with IC can only partially be attributed to impaired walking. It was concluded that patients who attain an acceptable walking capacity, QOL, and health status after six months may be encouraged to continue unsupervised exercise training. In contrast, patients who do not experience sufficient improvements after six months are unlikely to benefit from this form of treatment. As a consequence, invasive therapy may become the next treatment option. However, if treatment aims not only to improve walking, but also the QOL of patients with IC, modification of risk factors, treatment of comorbidity, and psychological and social support to accommodate with the impairments that are inherent to IC and not relieved by better walking may offer important benefits.

CHAPTER 10

SAMENVATTING VOOR DE NIET INGEWIJDE LEZER

SUMMARY FOR THE NON-EXPERT READER

Atherosclerose is een ongeneeslijke ziekte, die leidt tot vernauwing en afsluiting van slagaders in alle delen van het lichaam, waardoor organen onvoldoende van zuurstofrijk bloed worden voorzien. De kransslagaderen van het hart, de halsslagaderen en de slagaderen naar de benen zijn het vaakst aangetast. De meeste patiënten met atherosclerose overlijden aan een hartinfarct of een beroerte. Zeer slechte doorbloeding van de onderste ledematen kan tot verlies van een been leiden, maar dit komt weinig voor. In minder ernstige gevallen ontstaat na het lopen van een bepaalde afstand pijn in de benen, die verdwijnt wanneer gedurende enkele minuten rust wordt genomen. Dit ziektebeeld heet claudicatio intermittens (CI) of "een etalagebeen". Alhoewel CI dus een milde uiting is van atherosclerose, is het een teken van vaatlijden met potentieel levensbedreigende complicaties in andere organen. CI is dus een mild symptoom van een ernstige ziekte. De ontwikkelingen van vaatchirurgie (bypasses) en radiologie ("Dotteren") hebben ertoe geleid dat de behandeling van CI vooral gericht is op het herstel van doorbloeding en niet zozeer op de atherosclerotische risico's voor de levensverwachting en de kwaliteit van het resterend leven. De juistheid van een dergelijke benadering hangt af van de ernst van de handicap, het relatieve belang van andere aandoeningen en kenmerken van de patiënt. De ernst van CI en de resultaten van behandeling worden traditioneel uitgedrukt in (verbetering van) de loopafstand, de enkel-arm index (een maat voor de doorbloeding van de benen) en de duurzaamheid van het resultaat van operaties en Dotterbehandelingen. De patiënt met CI wordt vooral beperkt in zijn/haar functionele mogelijkheden als gevolg van de loopbeperking en veel voorkomende nevenaandoeningen (hoge bloeddruk, hartklachten, suikerziekte, longaandoeningen, nierziekten, etc.). Hoewel het risico om een been te verliezen klein is, vormt het onderliggend lijden, atherosclerose, een reële bedreiging voor de levensverwachting. De behandeling van patiënten met CI dient daarom niet alleen gericht te zijn op het verbeteren van de loopafstand, maar met name ook op de risicofactoren van atherosclerose (roken, cholesterol, gewicht) en nevenaandoeningen. Omdat de behandeling dus symptomatisch is ten aanzien van de loopbeperking en palliatief ten aanzien van het onderliggend lijden, is het van belang om naast de traditionele, klinische meetgegevens ook rekening te houden met de wijze waarop CI en de gevolgen van behandeling door de individuele patiënt ervaren worden. Omdat de huidige, klinische parameters die informatie niet geven, dienen er nieuwe methoden ontwikkeld en gebruikt te worden die rekening houden met het perspectief van de patiënt met CI als manifestatie van atherosclerotisch vaatlijden. Het meten van kwaliteit van leven (KvL) is een methode om dit perspectief te evalueren. Dit proefschrift gaat over KvL bij patiënten met CI en de rol die risicofactoren en nevenaandoeningen daarbij spelen.

De publicaties over KvL bij patiënten met CI gaan vaak over gezondheidstoestand in plaats van over KvL. Voor een juiste interpretatie is belangrijk de concepten goed te onderscheiden. Gezondheidstoestand is de objectieve waarneming van lichamelijk, geestelijk en sociaal functioneren. Door de Wereld Gezondheidsorganisatie (WHO) is KvL gedefinieerd als "de

waarneming die een individu heeft van zijn/haar positie in het leven, gezien in de context van de cultuur en de waardesystemen waarin hij/zij leeft en in relatie tot zijn/haar doelen, verwachtingen, normen en zorgen. Het is een breed concept dat op complexe wijze de individuele lichamelijke gezondheid, psychologische toestand, mate van onafhankelijkheid, sociale relaties, persoonlijke overtuigingen en verhouding tot omgevingsfactoren verenigt". Eenvoudig gezegd: KvL meet niet alleen functionele tekortkomingen, maar ook hoe die individueel ervaren worden. Bovendien houdt KvL ook rekening met omgevingsfactoren en met aspecten die niet direct gerelateerd zijn aan gezondheid.

Hoofdstuk 2 geeft, naast een overzicht van de definities van functionele toestand, gezondheidstoestand, KvL en respectieve meetinstrumenten, de resultaten van studies over KvL bij patiënten met CI. Uit het overzicht blijkt dat CI het dagelijks leven van de patiënt in brede zin beïnvloed. Toenemende CI leidt vooral tot verslechtering van de lichamelijke aspecten van KvL, terwijl behandeling tot verlichting van symptomen en beter lichamelijk functioneren kan leiden. Echter, het niveau van KvL na behandeling benadert slechts zelden het niveau van de gezonde bevolking. Ondanks de aandacht voor het onderwerp, weerspiegeld in een groot aantal publicaties over KvL voor en na behandeling, zijn er eigenlijk geen studies verschenen waarin KvL metingen gebruikt worden als richtlijn voor de klinische praktijk.

In een vooronderzoek werd, aan de hand van 22 patiënten met doorbloedingsstoornissen van de benen, de geschiktheid van de World Health Organisation Quality of Life Assessment Instrument-100 (WHOQOL-100) voor het meten van KvL bij patiënten met perifeer vernauwend vaatlijden bestudeerd. De WHOQOL-100 meet 24 facetten van KvL op zes domeinen (Lichamelijke en Psychologische gezondheid, Mate van onafhankelijkheid, Sociale relaties, Omgeving en Spiritualiteit) en een evaluerend facet Algemene KvL en gezondheid. Het instrument werd gekozen omdat het concept ervan de WHO-definitie van KvL het dichtst benadert. Het tweede doel van het vooronderzoek was de belasting, die het invullen van de volledige vragenlijst voor de patiënt betekent, terug te brengen door het instrument te beperken tot aspecten die, voor de betreffende patiëntengroep, relevante informatie verschaffen. Vanwege de gevestigde waarde die het meten van gezondheidstoestand bij patiënten met vernauwend vaatlijden heeft en de populariteit van het meetinstrument, is de RAND-36 eveneens aan de deelnemers voorgelegd. De RAND-36 is een instrument dat aan de hand van 36 vragen de gezondheidstoestand meet op acht domeinen (Fysiek functioneren, Sociaal Functioneren, Rolbeperkingen als gevolg van lichamelijke problemen, Rolbeperkingen als gevolg van emotionele problemen, Mentale gezondheid, Vitaliteit, Pijn en Algemene gezondheidsbeleving). Tevens worden gezondheidsveranderingen gedurende het voorgaande jaar geëvalueerd. Tenslotte is het eigenlijke invullen van de vragenlijsten door de patiënten door middel van observatie bestudeerd.

Beide meetinstrumenten zijn getest aan de hand van parameters voor de verdeling van antwoorden en interne consistentie, een maat voor de betrouwbaarheid van een instrument. Omdat voor een grote verscheidenheid van antwoorden een grote variatie in de ernst van het vaatlijden vereist was, is er voor gekozen om zowel patiënten met ernstig vaatlijden, een bedreigd been, als patiënten met minder ernstige klachten, het etalagebeen, in de studie op te nemen. De resultaten van het vooronderzoek, zoals beschreven in hoofdstuk 3, tonen dat de WHOQOL-100 voldoet voor het meten van KvL bij patiënten met vernauwend vaatlijden. Het instrument kon teruggebracht worden tot 16 van de oorspronkelijke 24 facetten betreffende de domeinen Lichamelijke gezondheid, Psychologische gezondheid, Mate van onafhankelijkheid, Sociale relaties, Omgeving en het evaluerende facet Algemene KvL en gezondheid. Hoewel de verdeling van antwoorden niet bevredigend was voor alle vragen van de RAND-36 is dit instrument niet gereduceerd, enerzijds omdat het al kort is en anderzijds omdat het reeds op grote schaal geaccepteerd is en gebruikt wordt. Tot slot zijn er aanbevelingen gedaan met betrekking tot praktische problemen die naar voren kwamen tijdens het invullen van de vragenlijsten door voornamelijk oudere patiënten.
In de literatuur over KvL bij patiënten met CI worden de termen gezondheidstoestand en KvL vaak zonder verdere toelichting gebruikt. In hoofdstuk 4 wordt getracht overeenkomsten en verschillen tussen gezondheidstoestand en KvL te beschrijven op basis van gegevens van de RAND-36 en de verkorte versie van de WHOQOL-100, zoals ingevuld door 200 patiënten met CI. De resultaten van beide instrumenten kwamen overeen met betrekking tot lichamelijke beperkingen, maar niet voor wat betreft sociaal functioneren en pijn. Patiënten met lage scores voor de RAND-36 domeinen Sociaal functioneren en Pijn bleken zich niet noodzakelijkerwijs ook sociaal beperkt te voelen of pijn als een groot probleem in het dagelijks leven te ervaren, zoals aangegeven in de WHOQOL. KvL meting gaf inzicht in de achtergronden van beperkingen zoals aangegeven in de RAND-36 domeinen Mentale gezondheid en Algemene gezondheidsbeleving. De evaluatie van omgevingsfactoren en van aspecten die niet direct aan gezondheid gerelateerd zijn, zoals opgenomen in de WHOQOL, bracht problemen aan het licht die in de gezondheidstoestand niet teruggevonden kunnen worden. Op basis van de vergelijking tussen KvL en gezondheidstoestand bij patiënten met CI is geconcludeerd dat de subjectieve evaluatie van KvL domeinen een toegevoegde waarde heeft ten opzichte van het louter registreren van functionele beperkingen. KvL meting zonder rekening te houden met individuele waarden van de patiënt met CI kan misleidend zijn en heeft het risico dat behandeling zich op verkeerde doelen richt.
De eerste publicatie (hoofdstuk 5) over CI en KvL, zoals gedefinieerd door de WHO, toonde een belangrijke invloed van CI op een scala van KvL facetten en domeinen. Patiënten evalueerden hun functioneren aanzienlijk slechter dan gezonden voor de domeinen Lichamelijke gezondheid en Mate van onafhankelijkheid. Bovendien ervoeren zij meer negatieve gevoelens en waren er beperkingen ten aanzien van recreatiemogelijkheden en

vervoer. Algemene KvL en gezondheid waren beduidend slechter dan bij gezonden. Verslechtering van CI bleek alleen van invloed op de score voor het facet Mobiliteit. De ernst van de overige KvL beperkingen was onafhankelijk van de ernst van CI. Dit suggereert dat succesvolle behandeling van CI, in de zin van een grotere loopafstand, slechts van beperkte betekenis zou zijn voor de algehele KvL. De grote afhankelijkheid van medicatie en behandelingen is niet direct gerelateerd aan de loopafstand en doet vermoeden dat nevenaandoeningen een belangrijke invloed hebben op de KvL van patiënten met CI.
Deze verrassende bevinding werd nader onderzocht in een studie naar de voorspellende waarde van de demografische variabelen leeftijd en geslacht, de ernst van de claudicatie, bekende risicofactoren voor hart- en vaatziekten, veel voorkomende nevenaandoeningen en de aanwezigheid van niet door vaatlijden veroorzaakte rug-, heup- en knieklachten.
Het bleek dat de gewrichtsklachten een enorme invloed hadden op vele aspecten van KvL. Patiënten met meer nevenaandoeningen hadden een slechtere algemene KvL, minder energie en voelden zich toenemend afhankelijk van medicatie en behandelingen. De ernst van de claudicatie was een statistisch significante voorspeller van KvL voor de WHOQOL facetten Mobiliteit, Alledaagse levensactiviteiten, Werkvermogen, Pijn en ongemak, Seksuele activiteit en Vervoer. Samenvattend heeft de studie aangetoond dat KvL bij patiënten met CI slechts ten dele wordt bepaald door de ernst van de loopbeperking. Gezien het grote belang van risicofactoren, nevenaandoeningen en bijkomende gewrichtsklachten voor KvL, dient bij het opstellen van een behandelplan voor de patiënt met CI met deze factoren rekening gehouden te worden.
De relatief bescheiden rol van de loopbeperking en de grote invloed van nevenaandoeningen op de KvL bij patiënten met CI lijken de terughoudendheid ten aanzien van chirurgische of endovasculaire behandeling, zoals tegenwoordig aanbevolen, te rechtvaardigen. Om de effecten op KvL, gezondheidstoestand en loopafstand te beoordelen, is een vervolgstudie gedaan bij patiënten met CI die conservatief zijn behandeld (hoofdstuk 7). Na een jaar van de meest basale vorm van conservatieve behandeling,"niet roken, maar lopen", bleek de loopafstand aanzienlijk toegenomen te zijn. Tegelijkertijd traden er verbeteringen op voor de facetten Mobiliteit en Pijn en ongemak (verkorte WHOQOL-100) en het domein Pijn (RAND-36). Het viel op dat de veranderingen in loopafstand, KvL en gezondheidstoestand zich alle voltrokken in de eerste zes maanden van de behandeling, waarna de scores zich gedurende minstens zes maanden op dat niveau handhaafden. Om een indruk te krijgen van het relatieve belang van de veranderende scores voor KvL en gezondheidstoestand, werden deze vergeleken met die van in leeftijd en geslacht overeenkomende gezonde personen. KvL scores bereikten het niveau van gezonden niet, maar daalden zelfs belangrijk voor het facet Positieve gevoelens, zowel na zes maanden als na een jaar, vergeleken met gezonden. De aanvankelijke overmaat aan negatieve gevoelens bij patiënten met CI nam geleidelijk af tot het niveau van gezonden. De scores voor het RAND-36 domein Pijn benaderden na een jaar

wel het niveau van gezonden. Ondanks een sterk verbeterde loopafstand bleven er na een jaar conservatieve behandeling onverminderd beperkingen ten aanzien van de KvL en de gezondheidstoestand. Dit bevestigt de conclusies van de hoofdstukken 5 en 6 dat een slechtere KvL bij patiënten met CI slechts ten dele toegeschreven kan worden aan een beperkt loopvermogen. Daarom kunnen patiënten, die een acceptabele loopafstand, KvL en gezondheidstoestand bereiken na zes maanden conservatieve behandeling, aangemoedigd worden om hiermee door te gaan. Bij patiënten die na zes maanden onvoldoende verbetering ervaren is het onwaarschijnlijk dat deze behandelingsvorm baat gaat geven. Een volgende stap zou dan een Dotterbehandeling of bypassoperatie kunnen zijn, vooropgesteld dat de omstandigheden dat toelaten. Indien echter het doel van de behandeling niet beperkt blijft tot het verbeteren van de loopafstand, maar ook gericht is op de KvL van patiënten met CI, kunnen behandeling van risicofactoren en nevenaandoeningen, maar ook psychologische en sociale steun gericht op beperkingen die niet verbeterd worden door een grotere loopafstand, de patiënt tot voordeel strekken.

APPENDIX I

WORLD HEALTH ORGANISATION QUALITY OF LIFE ASSESSMENT INSTRUMENT-100 (WHOQOL-100)

WERELD GEZONDHEIDS ORGANISATIE
KWALITEIT VAN LEVEN
VRAGENLIJST
WHOQOL-100

- facet 0 Algehele kwaliteit van leven en gezondheid
- **Domein I** **Lichamelijke gezondheid**
- facet 1 Pijn en ongemak
- facet 2 Energie en vermoeidheid
- facet 3 Slaap en rust
- **Domein II** **Psychologische gezondheid**
- facet 4 Positieve gevoelens
- facet 5 Cognitieve vermogens
- facet 6 Zelfwaardering
- facet 7 Lichaamsbeeld en uiterlijk
- facet 8 Negatieve gevoelens
- **Domein III** **Mate van onafhankelijkheid**
- facet 9 Mobiliteit
- facet 10 Alledaagse levensactiviteiten
- facet 11 Afhankelijkheid van medicatie en behandelingen
- facet 12 Werkvermogen
- **Domein IV** **Sociale relaties**
- facet 13 Persoonlijke relaties
- facet 14 Sociale steun
- facet 15 Sexuele activiteit
- **Domein V** **Omgeving**
- facet 16 Fysieke veiligheid
- facet 17 Woonomgeving
- facet 18 Financiële bronnen
- facet 19 Beschikbaarheid en kwaliteit van gezondheidszorg
- facet 20 Mogelijkheden om nieuwe informatie en vaardigheden te verwerven
- facet 21 Recreatie/ vrije tijd
- facet 22 Fysieke omgeving (vervuiling, lawaai, verkeer, klimaat)
- facet 23 Vervoer
- **Domein VI** **Spiritualiteit, religie, persoonlijke overtuigingen**

WERELD GEZONDHEIDS ORGANISATIE
KWALITEIT VAN LEVEN
VRAGENLIJST
WHOQOL-100

Instructies

Wij vragen u om in deze vragenlijst aan te geven wat u vindt van uw kwaliteit van leven, gezondheid en andere levensgebieden. Beantwoord alstublieft alle vragen. Als u onzeker bent over het antwoord dat u wilt geven op een vraag, kies dan het antwoord dat het meest toepasselijk lijkt. Dit kan vaak uw eerste reactie zijn.
Houd uw normen, hoop, genoegens en zorgen in gedachten. We vragen u te denken aan uw leven in de **afgelopen twee weken**.
Bijvoorbeeld, met betrekking tot de laatste twee weken, zou een vraag kunnen luiden:
Hoeveel zorgen maakt u zich over uw gezondheid?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

U moet het cijfer omcirkelen dat het beste past bij hoe vaak u zich in de afgelopen twee weken zorgen heeft gemaakt over uw gezondheid. Dus u moet het cijfer 4 omcirkelen, als u zich veel ("Hevig") zorgen heeft gemaakt over uw gezondheid, of het cijfer 1 "Helemaal Niet" als u zich helemaal geen zorgen heeft gemaakt over uw gezondheid. Leest u alstublieft elke vraag, ga uw gevoelens na en omcirkel voor elke vraag het cijfer van de schaal dat het beste bij u past.

Dank u voor uw hulp.

In de volgende vragen wordt gevraagd **in welke mate (hoeveel)** u in de afgelopen twee weken bepaalde dingen hebt ervaren, bijvoorbeeld positieve gevoelens zoals geluk en tevredenheid. Als u deze in een extreme hoeveelheid hebt ervaren, omcirkel dan het cijfer 5 onder "Een Extreme Hoeveelheid". Als u dergelijke zaken helemaal niet hebt ervaren, omcirkel dan het cijfer 1 onder "Helemaal Niet". De tussenliggende cijfers kunt u gebruiken om aan te geven dat het ergens tussen "Helemaal Niet" en "Helemaal" in ligt. Vragen verwijzen naar de afgelopen twee weken.

F1.2 *Maakt u zich zorgen over uw pijn of ongemak?*

Helemaal niet				Een extreme hoeveelheid
1	2	3	4	5

F1.3 *Hoe moeilijk is het voor u om om te gaan met pijn of ongemak?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F1.4 *In welke mate vindt u dat pijn u afhoudt van wat u moet doen?*

Helemaal niet				Een extreme hoeveelheid
1	2	3	4	5

F2.2 *Hoe gemakkelijk raakt u vermoeid?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F3.2 *In welke mate hebt u problemen met slapen?*

Helemaal Niet				Een extreme hoeveelheid
1	2	3	4	5

F3.4 *Hoeveel zorgen maakt u zich over enigerlei problemen met slapen?*

Helemaal niet				Een extreme hoeveelheid
1	2	3	4	5

F4.1 *Hoeveel geniet u van het leven?*

Helemaal niet *Weinig* *Middelmatig* *Hevig* *Een extreme hoeveelheid*

1 *2* *3* *4* *5*

F4.3 *Hoe positief ziet u uw toekomst?*

Helemaal niet *Bijna niet* *Gemiddeld* *Nogal* *Helemaal*

1 *2* *3* *4* *5*

F4.4 *Hoezeer ervaart u positieve gevoelens in uw leven?*

Helemaal niet *Weinig* *Middelmatig* *Hevig* *Een extreme hoeveelheid*

1 *2* *3* *4* *5*

F5.3 Hoe goed kunt u zich concentreren?

Helemaal niet Bijna niet Gemiddeld Nogal Helemaal

1 2 3 4 5

F6.1 *Heeft u waardering voor uzelf?*

Helemaal niet *Weinig* *Middelmatig* *Hevig* *Een extreme hoeveelheid*

1 *2* *3* *4* *5*

F6.2 *Hoeveel vertrouwen hebt u in uzelf?*

Helemaal niet *Weinig* *Middelmatig* *Hevig* *Een extreme hoeveelheid*

1 *2* *3* *4* *5*

F7.2 Voelt u zich geremd door uw uiterlijk?

Helemaal niet Bijna niet Gemiddeld Nogal Helemaal

1 2 3 4 5

F7.3 Is er iets in uw uiterlijk op grond waarvan u zich ongemakkelijk voelt?

Helemaal Niet Weinig Middelmatig Hevig Een extreme hoeveelheid

1 2 3 4 5

F8.2 *Hoe bezorgd voelt u zich?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F8.3 *Hoezeer verstoren gevoelens van droefheid of depressie uw alledaagse functioneren?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F8.4 *Hoeveel last hebt u van depressieve gevoelens?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F10.2 *In welke mate hebt u moeilijkheden met het doen van uw routine-activiteiten?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F10.4 *Hoeveel hinder ondervindt u van allerlei beperkingen in het doen van alledaagse levensactiviteiten?*

Helemaal Niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F11.2 *Hoeveel behoefte hebt u aan enigerlei medicatie om in uw dagelijkse leven te kunnen functioneren?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F11.3 *Hoeveel behoefte hebt u aan medische behandeling om in uw dagelijkse leven te kunnen functioneren?*

Helemaal Niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F11.4 *In welke mate hangt uw kwaliteit van leven af van het gebruik van medicijnen of medische hulpmiddelen?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F13.1 *Hoe alleen voelt u zich in uw leven?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F15.2 *Hoe goed zijn uw seksuele behoeften vervuld?*

Helemaal Niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F16.1 Hoe veilig voelt u zich in uw dagelijkse leven?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F16.2 Vindt u dat u in een veilige omgeving woont?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F16.3 Hoeveel zorgen maakt u zich over uw veiligheid?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F17.4 *Hoe erg bevalt het u waar u woont?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F18.2 Hebt u financiële moeilijkheden?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F18.4 Hoeveel zorgen maakt u zich over geld?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F19.1 Hoe gemakkelijk kunt u goede medische zorg krijgen?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F21.3 Hoeveel geniet u van uw vrije tijd?

Helemaal niet	*Weinig*	*Middelmatig*	*Hevig*	*Een extreme hoeveelheid*
1	*2*	*3*	*4*	*5*

F22.1 Hoe gezond is uw omgeving?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F22.2 Hoeveel zorgen heeft u over het lawaai in het gebied waarin u woont?

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F23.2 In welke mate hebt u problemen met vervoer?

Helemaal niet	*Weinig*	*Middelmatig*	*Hevig*	*Een extreme hoeveelheid*
1	*2*	*3*	*4*	*5*

F23.4 Hoe erg beperken moeilijkheden met vervoer uw leven?

Helemaal niet	*Weinig*	*Middelmatig*	*Hevig*	*Een extreme hoeveelheid*
1	*2*	*3*	*4*	*5*

F2.4 *Heeft u last van vermoeidheid?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F15.4 *Heeft u last van moeilijkheden in uw seksleven?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

In de volgende vragen wordt gevraagd naar **de mate waarin** u bepaalde dingen ervaart of in staat was te doen in de afgelopen twee weken, bijvoorbeeld alledaagse activiteiten zoals wassen, aankleden of eten. Als u in staat bent geweest deze dingen helemaal te doen, omcirkel dan het cijfer 5 onder "Helemaal". Als u niet in staat bent geweest om al deze dingen te doen, omcirkel dan het cijfer 1 onder "Helemaal niet". De tussenliggende cijfers kunt u gebruiken om aan te geven dat het ergens tussen "Helemaal Niet" en "Helemaal" in ligt. Vragen verwijzen naar de afgelopen twee weken.

F2.1 *Hebt u genoeg energie voor het leven van alledag?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F7.1 Kunt u uw lichamelijke uiterlijk accepteren?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F10.1 *In welke mate kunt u uw dagelijkse dingen doen?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F11.1 *Hoe afhankelijk bent u van medicaties?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F14.1 Krijgt u het soort steun dat u nodig hebt, van anderen?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F14.2 In welke mate kunt u rekenen op uw vrienden als u ze nodig hebt?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F17.1 Hoe comfortabel is de plaats waar u woont?

Helemaal niet	*Weinig*	*Middelmatig*	*Hevig*	*Een extreme hoeveelheid*
1	*2*	*3*	*4*	*5*

F17.2 In welke mate komt de kwaliteit van uw huis tegemoet aan uw behoeften?

Helemaal niet	*Bijna niet*	*Gemiddeld*	*Nogal*	*Helemaal*
1	*2*	*3*	*4*	*5*

F18.1 Hebt u genoeg geld om in uw behoeften te voorzien?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F20.1 Hoe beschikbaar voor u is de informatie, die u nodig hebt in uw dagelijkse leven?

Helemaal niet	*Bijna niet*	*Gemiddeld*	*Nogal*	*Helemaal*
1	*2*	*3*	*4*	*5*

F20.2 In welke mate hebt u mogelijkheden om de informatie te verkrijgen waarvan u vindt dat u die nodig heeft?

Helemaal niet	*Bijna niet*	*Gemiddeld*	*Nogal*	*Helemaal*
1	*2*	*3*	*4*	*5*

F21.1 *Hebt u mogelijkheden tot recreatie?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F21.2 Hoe goed kunt u zich ontspannen en uzelf vermaken?

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F23.1 *In welke mate hebt u geschikte middelen van vervoer?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

In de volgende vragen wordt gevraagd naar hoe **tevreden of ontevreden** u in de afgelopen twee weken bent geweest met de verschillende aspecten van uw leven; bijvoorbeeld, uw familieleven of uw vermogen om met degenen om u heen te communiceren. Beslis hoe tevreden of ontevreden u bent met elk aspect van uw leven en omcirkel het cijfer dat het beste past bij wat u hierover vindt.

G2 *Hoe tevreden bent u met de kwaliteit van uw leven?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

G3 *Hoe tevreden bent u met uw leven in het algemeen?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

G4 *Hoe tevreden bent u met uw gezondheid?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F2.3 *Hoe tevreden bent u met de energie die u heeft?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F3.3 *Hoe tevreden bent u met uw slaap?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F5.2 Hoe tevreden bent u met uw vermogen om nieuwe informatie te leren?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F5.4 Hoe tevreden bent u met uw vermogen om beslissingen te nemen?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F6.3 *Bent u tevreden met uzelf?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F6.4 *Hoe tevreden bent u met uw bekwaamheden?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F7.4 Hoe tevreden bent u met uw uiterlijk?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F10.3 *Bent u tevreden met uw vermogen om alledaagse activiteiten te verrichten?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F13.3 *Hoe tevreden bent u met uw persoonlijke relaties?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F15.3 *In welke mate bent u tevreden met uw sexuele leven?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F14.3 Hoe tevreden bent u met de steun die u krijgt van uw familie?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F14.4 Hoe tevreden bent u met de steun die u krijgt van uw vrienden?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F13.4 *Hoe tevreden bent u met uw vermogen om voor anderen te zorgen of hen steun te geven?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F16.4 Hoe tevreden bent u met uw lichamelijke veiligheid?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F17.3 *Bent u tevreden met uw leefomstandigheden?*

Erg ontevreden	*Ontevreden*	*Tevreden noch ontevreden*	*Content*	*Erg tevreden*
1	*2*	*3*	*4*	*5*

F18.3 Hoe tevreden bent u met uw financiële situatie?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F19.3 Hoe tevreden bent u met uw toegang tot gezondheidsdiensten?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F19.4 Hoe tevreden bent u met de sociale diensten?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F20.3 *Bent u tevreden met uw mogelijkheden om nieuwe vaardigheden te verwerven?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F20.4 *Bent u tevreden met uw mogelijkheden om nieuwe informatie te verwerven?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F21.4 *Hoe tevreden bent u met de manier waarop u uw vrije tijd doorbrengt?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F22.3 Hoe tevreden bent u met uw natuurlijke omgeving (bijv. vervuiling, klimaat, lawaai, aantrekkelijkheid)?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F22.4 Hoe tevreden bent u met het klimaat in het gebied waarin u woont?

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F23.3 *Hoe tevreden bent u met uw vervoer?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F13.2 *Voelt u zich gelukkig met uw relatie met uw familieleden?*

Erg ongelukkig	Tamelijk ongelukkig	Gelukkig noch ongelukkig	Tamelijk gelukkig	Erg gelukkig
1	2	3	4	5

G1 *Hoe zou u uw kwaliteit van leven inschatten?*

Erg slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

F15.1 *Hoe zou u uw seksleven beoordelen?*

Erg slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

F3.1 *Hoe goed slaapt u?*

Erg slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

F19.2 Wat vindt u van de kwaliteit van de sociale diensten die u ter beschikking staan?

Erg slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

F5.1 Hoe zou u uw geheugen beoordelen?

Erg slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

De volgende vragen verwijzen naar **hoe vaak** u bepaalde dingen hebt gevoeld of ervaren, bijvoorbeeld de steun van uw familie of vrienden of negatieve ervaringen, zoals zich onveilig voelen. Als u deze dingen helemaal niet heeft ervaren in de afgelopen twee weken, omcirkel dan het cijfer 1 onder "Nooit". Als u deze dingen wel heeft ervaren, beslis dan hoe vaak en omcirkel het toepasselijke cijfer. Dus, bijvoorbeeld, als u de afgelopen twee weken de hele tijd pijn hebt ervaren, omcirkel dan het cijfer 5 onder "Altijd". Vragen verwijzen naar de afgelopen twee weken.

F1.1 *Hoe vaak heeft u een gevoel van pijn gehad?*

Nooit	Zelden	Zo nu en dan	Redelijk vaak	Altijd
1	2	3	4	5

F4.2 *Voelt u zich over het geheel genomen tevreden?*

Nooit	Zelden	Zo nu en dan	Redelijk vaak	Altijd
1	2	3	4	5

F8.1 *Hoe vaak heeft u negatieve gevoelens, zoals een sombere stemming, wanhoop, angst, depressie?*

Nooit	Zelden	Zo nu en dan	Redelijk vaak	Altijd
1	2	3	4	5

De volgende vragen verwijzen naar alle soorten **"werk"** die u verricht. Werk betekent hier elke redelijk omvangrijke activiteit die u verricht. Dit omvat vrijwilligerswerk, voltijds studeren, zorgen voor het huis, zorgen voor kinderen, betaald werk, onbetaald werk. Dus werk, zoals het hier wordt gebruikt, slaat op die activiteiten waarvan u vindt dat ze een groot deel van uw tijd en energie innemen. Vragen verwijzen naar de afgelopen twee weken.

F12.1 *Bent u in staat om uw werkzaamheden te verrichten?*

Helemaal Niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F12.2 *Voelt u zich in staat om aan uw dagelijkse verplichtingen te voldoen?*

Helemaal niet	Bijna niet	Gemiddeld	Nogal	Helemaal
1	2	3	4	5

F12.4 *Bent u tevreden met uw werkvermogen?*

Erg ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F12.3 *Hoe zou u uw werkvermogen inschatten?*

Erg Slecht	Tamelijk slecht	Goed noch slecht	Tamelijk goed	Erg goed
1	2	3	4	5

In de volgende vragen wordt gevraagd naar **hoe goed u in staat was om zich te verplaatsen** in de afgelopen twee weken. Dit verwijst naar uw lichamelijk vermogen om uw lichaam te bewegen op zo'n manier dat het u in staat stelt rond te lopen en de dingen te doen die u zou willen doen, alsook de dingen die u moet doen.

F9.3 *Hoeveel last hebt u van problemen bij het zich verplaatsen?*

Helemaal niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F9.4 *In welke mate beïnvloeden moeilijkheden met beweging uw manier van leven?*

Helemaal Niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

F9.2 *Hoe tevreden bent u met de manier waarop u in staat bent zich te verplaatsen?*

Erg Ontevreden	Ontevreden	Tevreden noch ontevreden	Content	Erg tevreden
1	2	3	4	5

F9.1 *Hoe goed kunt u zich verplaatsen?*

Helemaal Niet	Weinig	Middelmatig	Hevig	Een extreme hoeveelheid
1	2	3	4	5

De volgende paar vragen gaan over uw **persoonlijke overtuigingen** en hoe deze uw leven beïnvloeden. Deze vragen verwijzen naar geloof, spiritualiteit of enigerlei andere overtuigingen die u zou kunnen hebben. Opnieuw verwijzen deze vragen naar de laatste twee weken.

F24.1 Geven uw persoonlijke overtuigingen betekenis aan uw leven?

Helemaal Niet				Een extreme hoeveelheid
1	2	3	4	5

F24.3 In welke mate geven uw persoonlijke overtuigingen u de kracht om moeilijkheden aan te kunnen?

Helemaal Niet				Een extreme hoeveelheid
1	2	3	4	5

F24.4 In welke mate helpt uw persoonlijke geloof u om moeilijkheden in het leven te begrijpen?

Helemaal niet				Een extreme hoeveelheid
1	2	3	4	5

F24.2 In welke mate voelt u dat uw leven betekenisvol is?

Helemaal niet				Een extreme hoeveelheid
1	2	3	4	5

De vragen die deel uit maken van de, voor patiënten met perifeer arterieel occluderend vaatlijden, gereduceerde versie zijn cursief gedrukt.

APPENDIX II

RAND-36 ITEM HEALTH SURVEY 1.0

RAND-36

Toelichting

In de vragenlijst wordt naar uw gezondheid gevraagd. Wilt u elke vraag beantwoorden door het juiste hokje aan te kruisen? Wanneer u twijfelt over het antwoord op een vraag, probeer dan het antwoord te geven dat het meest van toepassing is.

1. Wat vind u, over het algemeen genomen, van uw gezondheid?

Uitstekend	O
Zeer goed	O
Goed	O
Matig	O
Slecht	O

2. **In vergelijking met een jaar geleden,** hoe zou u nu uw gezondheid in het algemeen beoordelen?

Veel beter dan een jaar geleden	O
Iets beter dan een jaar geleden	O
Ongeveer hetzelfde als een jaar geleden	O
Iets slechter dan een jaar geleden	O
Veel slechter dan een jaar geleden	O

3. De volgende vragen gaan over dagelijkse bezigheden.
   Wordt u door uw gezondheid **op dit moment** beperkt bij deze bezigheden? Zo ja, in welke mate?

	Ja, ernstig beperkt	Ja, een beetje beperkt	Nee, helemaal niet beperkt
a. *forse inspanning*,zoals hardlopen, zware voorwerpen tillen, inspannend sporten	O	O	O
b. *Matig inspanning*, zoals het verplaatsen van een tafel, stofzuigen, fietsen	O	O	O
c. Tillen of boodschappen dragen	O	O	O
d. *Een paar* trappen lopen	O	O	O
e. E*en trap* lopen	O	O	O
f. Buigen, knielen of bukken	O	O	O
g. *Meer dan een kilometer* lopen	O	O	O
h. *Een halve kilometer* lopen	O	O	O
i *Honderd meter* lopen	O	O	O
j. Uzelf wassen of aankleden	O	O	O

4. Had u ten gevolge van uw lichamelijke gezondheid, **de afgelopen 4 weken** een van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

	Ja	Nee
a. U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden	O	O
b. U heeft *minder bereikt* dan u zou willen	O	O
c. U was beperkt in het *soort* werk of het soort bezigheden	O	O
d. U had moeite met het werk of andere bezigheden (het kostte u bijvoorbeeld extra inspanning)	O	O

5. Had u, ten gevolge van een emotioneel probleem (bijvoorbeeld doordat u zich depressief of angstig voelde), **de afgelopen 4 weken** een van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

	Ja	Nee
a. U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden	O	O
b. U heeft *minder bereikt dan* u zou willen	O	O
c. U heeft het werk of andere bezigheden niet zo zorgvuldig gedaan als u gewend bent	O	O

6. In hoeverre heeft uw lichamelijke gezondheid of hebben uw emotionele problemen u **de afgelopen 4 weken** belemmerd in uw normale sociale bezigheden met gezin, vrienden, buren of anderen?

Helemaal niet	O
Enigszins	O
Nogal	O
Veel	O
Heel erg veel	O

7. Hoeveel pijn had u **de afgelopen 4 weken**?

Geen	O
Heel licht	O
Licht	O
Nogal	O
Ernstig	O
Heel ernstig	O

8. In welke mate heeft pijn u **de afgelopen 4 weken** belemmerd bij uw normale werkzaamheden (zowel werk buitenshuis als huishoudelijk werk)?

Helemaal niet	O
Een klein beetje	O
Nogal	O
Veel	O
Heel erg veel	O

9. Deze vragen gaan over hoe u zich **de afgelopen 4 weken** heeft gevoeld. Wilt u bij elke vraag het antwoord aankruisen dat het beste aansluit bij hoe u zich heeft gevoeld?

Hoe vaak gedurende **de afgelopen 4 weken**

	Voortdurend	Meestal	Vaak	Soms	Zelden	Nooit
a. Voelde u zich levenslustig?	O	O	O	O	O	O
b. Voelde u zich erg zenuwachtig?	O	O	O	O	O	O
c. Zat u zo erg in de put dat niets u kon opvrolijken?	O	O	O	O	O	O
d. Voelde u zich kalm en rustig?	O	O	O	O	O	O
e. Voelde u zich energiek?	O	O	O	O	O	O
f. Voelde u zich neerslachtig en somber?	O	O	O	O	O	O
g. Voelde u zich uitgeblust?	O	O	O	O	O	O
h. Voelde u zich gelukkig?	O	O	O	O	O	O
i. Voelde u zich moe?	O	O	O	O	O	O

10. Hoe vaak hebben uw lichamelijke gezondheid of emotionele problemen gedurende **de afgelopen 4 weken** uw sociale activiteiten (zoals bezoek aan vrienden) belemmerd?

Voortdurend	O
Meestal	O
Soms	O
Zelden	O
Nooit	O

11. Wilt u het antwoord kiezen dat het beste weergeeft hoe juist of onjuist u elk van de volgende uitspraken voor uzelf vindt?

	volkomen juist	groten-deels juist	weet ik niet	groten-deels onjuist	volkomen onjuist
a. Ik lijk gemakkelijker ziek te worden dan andere mensen	O	O	O	O	O
b. Ik ben net zo gezond als andere mensen die ik ken	O	O	O	O	O
c. Ik verwacht dat mijn gezondheid achteruit zal gaan	O	O	O	O	O
d. Mijn gezondheid is uitstekend	O	O	O	O	O

Deze lijst betreft een Nederlandse vertaling van de RAND-36 item health survey 1.0 (RAND, 1992)

APPENDIX III

GRADING SYSTEM FOR CARDIOVASCULAR RSIK FACTORS AND COMORBIDITY OF THE SOCIETY FOR VASCULAR SURGERY/ INTERNATIONAL SOCIETY FOR CARDIOVASCULAR SURGERY (NORTH -AMERICAN CHAPTER)

Appendix 3

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity:

Diabetes mellitus: 0 = none. 1 = adult onset, controlled by diet or oral agents. 2 = adult onset, insulin controlled. 3 = juvenile onset.

Tobacco use: 0 = none or none for last 10 years. 1 = none current, but smoked in last 10 years. 2 = current (includes abstinence less than 1 year), less than 1 pack/day. 3 = current, greater than 1 pack/day.

Hypertension: 0 = diastolic usually lower than 90 mm Hg. 1 = controlled with a single drug. 2 = controlled with two drugs. 3 = requires more than two drugs, or is uncontrolled.

Hyperlipidemia: 0 = cholesterol (low density lipoprotein and total) and triglyceride levels within normal limits for age. 1 = readily controllable by diet. 2 = requiring strict dietary control. 3 = same as mild, but severe enough to require dietary and drug control.

Cardiac status: 0 = asymptomatic with normal electrocardiogram (ecg). 1 = asymptomatic, but with either remote myocardiac infarction (MI) by history (> 6 months), occult MI by ecg, or fixed defect on dipyridamole thallium or similar scan. 2 = any one of the following: stable angina, no angina, but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia ($\geq$ 1% of the time) on Holter monitoring, ejection fraction 25-45%, controlled ectopy or asymptomatic arrythmia, history of congestive heart failure that is now well compensated. 3 = any one of the following: unstable angina, symptomatic or poorly controlled ectopy/arrhythmia (chronic/recurrent), poorly compensated or recurrent congestive heart failure, ejection fraction less than 25%, myocardial infarction within 6 months.

Carotid disease: 0 = no symptoms, no evidence of disease; 1 = *asymptomatic* but with evidence of disease determined by duplex scan or other accepted noninvasive test or arteriogram; 2 = transient or temporary stroke; 3 = completed stroke with permanent neurologic deficit or acute stroke.

Renal status: (refers to stable levels, not transient drops or elevations in response to intravenous medication, hydration, or contrast media) 0 = no known renal disease, normal serum creatinine level; 1 = moderately elevated creatinine level, as high as 2.4 mg/dl; 2 = creatinine level, 2.5 to 5.9 mg/dl; 3 = creatinine level greater than 6.0 mg/dl, or on dialysis or with kidney transplant.

Pulmonary status: 0 = asymptomatic, normal chest x-ray film, pulmonary function tests within 20% of predicted; 1 = asymptomatic or mild dyspnea on exertion, mild chronic parenchymal x-ray changes, pulmonary function tests 65% to 80% of predicted; 2 = between 1 and 3; 3 = vital capacity less than 1.85 L, FEV_1 less than 1.2 L or less than 35% of predicted, maximal voluntary ventilation less than 50% of predicted, Pco_2 greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension.

ACKNOWLEDGEMENTS

I am greatly indebted to prof. dr. G.L.M. van Heck, dr. J. de Vries, and dr. J.F. Hamming for their support in conducting the study and for their comments in the preparation of the thesis. Besides, I would like to thank the members of the reviewing committee: prof. dr. J.K.I. Denollet, prof. dr. D.A. Legemate, prof. dr. J.A. Rauwerda, prof. dr. A.J.J.M. Vingerhoets, and dr. P.H.G.M. Soons, the surgical and secretarial staffs of the St. Elisabeth Hospital in Tilburg and the Martini Hospital in Groningen, the staff of the vascular outpatient clinic of the St. Elisabeth Hospital in Tilburg, the research assistant drs. A.E.A.M. Aquarius, and all others who have contributed to the study.

Thank you all.

ABOUT THE AUTHOR

The author was born in Amsterdam on March 30th 1960. After graduating in medicine at the University of Amsterdam in 1987, he specialised in general surgery in Antwerp, Belgium, at the affiliated hospitals of Antwerp University (1990-1996), followed by further training in vascular surgery as fellow at the St. Elisabeth Hospital in Tilburg (1997-1999). Presently, the author practices as a consultant in general and vascular surgery at the Martini Hospital in Groningen.

Stellingen

behorend bij het proefschrift

Quality of Life and Health Status

in Patients with Intermittent Claudication

1. De kwaliteit van leven van patiënten met claudicatio intermittens wordt slechts ten dele bepaald door de loopbeperking; van inspanningen die gericht zijn op het vergroten van de loopafstand mag dus slechts een beperkt effect op de algehele kwaliteit van leven verwacht worden. (dit proefschrift)

2. Naast het verbeteren van de loopafstand zijn de behandeling van nevenaandoeningen, psychologische aanpassingen en steun vanuit de sociale omgeving instrumenten die kunnen bijdragen aan het behoud en de verbetering van de kwaliteit van leven van patiënten met claudicatio intermittens. (dit proefschrift)

3. De objectieve ernst van functionele beperkingen komt bij patiënten met claudicatio intermittens slechts ten dele overeen met de mate waarin deze als belemmerend ervaren worden. (dit proefschrift)

4. Wanneer een patiënt met claudicatio intermittens na zes maanden conservatieve behandeling een aanvaardbare loopafstand en kwaliteit van leven heeft en wanneer bovendien nevenaandoeningen en risicofactoren adequaat behandeld zijn, is er geen reden tot voortgezette specialistische controle. (dit proefschrift)

5. De inspanningen om patiënten met claudicatio intermittens te overtuigen van het relatieve belang van de presenterende klacht ten opzichte van de levensbedreigende complicaties van voortschrijdende vaatziekte dienen vooral de kwantiteit en niet zozeer de kwaliteit van het resterend leven.

6. Het besef dat inspanningsgebonden pijn in de benen bijzaak is in het kader van een chronische, levensbedreigende aandoening heeft meetbare effecten op de kwaliteit van leven van patiënten met claudicatio intermittens. (dit proefschrift)

7. De wettelijk verplichte voorlichting over risico's en gevolgen van en alternatieven voor een bepaalde ingreep leidt dikwijls tot verwarring en het verzoek dat te doen wat de dokter het beste vindt.

8. Een zieke is vaak niet mondig maar bang en verdient aandacht en hulp bij het nemen van levensbepalende beslissingen.

9. Zich bekommeren om kwaliteit van leven is voorbehouden aan hen die zich verzekerd weten van de primaire levensbehoeften.

10. Draaglijk wordt het leven door het te aanvaarden zoals het is; er niet in berusten verhoogt wellicht de kwaliteit.

J.C. Breek, januari 2004